

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products)
Liability Litigation,) MD 15-02641-PHX-DGC
)
_____)
)
Lisa Hyde and Mark Hyde, a married) Phoenix, Arizona
couple,) September 27, 2018
)
Plaintiffs,)
)
v.) CV 16-00893-PHX-DGC
)
C.R. Bard, Inc., a New Jersey)
corporation, and Bard Peripheral)
Vascular, an Arizona corporation,)
)
Defendants.)
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 8 - A.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

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EXHIBITS**NUMBER****DESCRIPTION****PAGE**

5339 Jan. 15, 2008 FDA Clearance
Letter G2 Filter Retrievable
(K073090) (Substantial
Equivalence) 1582

5340 Oct. 31, 2007 BPV's G2 Filter
Retrieval Traditional
510(k) (K073090) 1588

7411 2008 Surgeon General's Call
to Action re PE and DVT 1608

5877 1996 Memo from Veronica Price 1630

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: I want to talk first about the motion for mistrial that was made yesterday.

My understanding is that the defendants' motion is based on three categories of references in the trial. The first is the references, two references, to the Booker trial by Plaintiffs' counsel when questioning witnesses and one reference to a trial transcript while questioning a witness. There was also a witness who referred to "other cases."

The second is that the bottom of some of the exhibit pages had a reference to a Maricopa County Superior Court case protective order.

And the third is the fact that the G2 evidence that I had excluded as hearsay was displayed and highlighted to the jury in the videotape.

Have I covered accurately the grounds for the motion, Mr. Rogers?

MR. ROGERS: Yes, Your Honor.

THE COURT: Do you wish to have a corrective

08:31:53 1 instruction on any of those items?

2 MR. ROGERS: No, Your Honor. I believe, as we've
3 discussed previously, I think that the instruction would just
4 draw unnecessary attention to it and make the whole situation
08:32:06 5 that much worse. That's why we felt compelled that we had to
6 move for mistrial.

7 THE COURT: Okay. The test, I believe, in the Ninth
8 Circuit for whether or not a mistrial should be granted is
9 whether the improper reference to evidence or the improper
08:32:25 10 comment viewed in the context of the entire trial more likely
11 than not would materially affect the verdict. I'm getting
12 that language from *United States versus Lemus*, L-E-M-U-S, 847
13 F.3d 1016, and the statement specifically is on page 1024. It
14 is a 2016 decision of the Ninth Circuit.

08:32:52 15 My conclusion, having looked over this evidence, is
16 that it would not materially affect the verdict in this case.

17 My reasons for that conclusion are the following:
18 There have been references to the Booker trial and to trial
19 transcripts and to a protective order in another case, all of
08:33:16 20 which could suggest to the jury there have been other cases.
21 However, I have instructed the jury repeatedly that they're
22 not to do any research on their own or to look at any other
23 matters. I've also instructed them that the statements by
24 lawyers are not evidence. I trust the jury is going to follow
08:33:35 25 the instructions. And there's been nothing said about the

08:33:39 1 other cases, whether they're against Bard, whether they're
2 against other manufacturers, that, in my view, would cause an
3 effect upon the verdict.

4 In fact, I believe it was defense counsel who
08:33:50 5 specifically brought up trials against Cook in the questioning
6 of one of the witnesses.

7 So the fact that there are other trials related to
8 filter issues I don't think would have an effect upon the
9 outcome of the case.

08:34:07 10 With respect to the G2 reference that was hearsay, I
11 don't think that will affect the verdict either. There is
12 going to be a lot of evidence on each side of the case as to
13 what was the identity of the filter at issue in this case.
14 The fact that there was one reference to a G2 that the jury
08:34:26 15 should not have seen but did see, in my view, won't tip the
16 balance in that analysis if the jurors actually read it. It
17 was on the screen clearly, but there was no testimony about
18 it.

19 So I can't conclude, given the fact there's lots of
08:34:41 20 other evidence on this issue, that that exposure is going to
21 materially affect the verdict.

22 And, therefore, I cannot conclude that this evidence
23 and these comments are likely to materially affect the verdict
24 and I'm going to deny the motion for mistrial.

08:35:00 25 The bigger problem with these references, in my view,

08:35:03 1 is not the effect they had on the jury, but they were clear
2 violations of my very clear orders. That should not have
3 happened. I don't think they're excusable. We've talked
4 about that at sidebar.

08:35:15 5 Plaintiffs' counsel, and all counsel, have pledged to
6 avoid those problems in it the future. I trust that will
7 happen.

8 But the fact that they were violations of my order is
9 not, in my judgment, a ground for mistrial. The question is
08:35:29 10 what effect it would have on the jury. And I can't conclude
11 that it would materially affect the verdict. So I'll deny the
12 motion for that reason.

13 We've handed you this morning proposed verdict form
14 and proposed instructions. Please be ready to discuss those
08:35:49 15 Tuesday evening. I'm moving my hearing on Tuesday so that at
16 4:30 on Tuesday we'll be able to talk about instructions.

17 I do have one question that I didn't note on what was
18 handed out, and that is whether we should give Instruction
19 Number 7 or modify it in light of the fact that Dr. Parisian
08:36:08 20 is testifying. That's the instruction about FDA -- former FDA
21 personnel not testifying. Do we just take it out? Do we
22 modify it in some respect? I would be interested in your
23 thoughts on that.

24 I'm happy to hear your thoughts on any of the other
08:36:27 25 instructions that you wish to comment on when we talk about

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

08:36:29 1 them on Tuesday evening.

2 Are there matters Plaintiffs' counsel want to raise
3 before we get started this morning?

4 MR. O'CONNOR: Nothing from our side, Your Honor.

08:36:41 5 Thank you.

6 THE COURT: How about from defense counsel?

7 MR. ROGERS: No, Your Honor.

8 THE COURT: Okay. We will plan to start at 9
9 o'clock, then, when we get the jury.

08:36:49 10 MR. LOPEZ: Thank you, Your Honor.

11 (Recess taken from 8:36 to 08:58. Proceedings resumed in
12 open court with the jury present.)

13 THE COURT: Thank you, please be seated.

14 Good morning, ladies and gentlemen.

08:59:24 15 JURORS: Good morning.

16 THE COURT: We will continue this morning with the
17 testimony of Dr. Parisian.

18 MR. LOPEZ: Thank you, Your Honor.

19 **SUZANNE PARISIAN, MD,**

08:59:34 20 recalled as a witness herein, after having been previously
21 sworn or affirmed, was examined and testified as follows:

22 D I R E C T E X A M I N A T I O N (CONTINUED)

23 BY MR. LOPEZ:

24 Q Good morning, Dr. Parisian.

08:59:36 25 A Good morning.

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

08:59:37 1 Q Yesterday we spoke a little bit about the EVEREST trial.

2 Do you recall that?

3 A Yes, sir.

4 Q And was the safety of G2 as a permanent device on the
08:59:47 5 table with respect to that study?

6 A No. It was a proof of concept to look at retrievability.

7 Q Was it a study to determine the safety, complication
8 rates, or a reconsideration by FDA of the prior clearance as a
9 permanent device?

09:00:04 10 A No.

11 Q Was that the sole issue that FDA was looking at? And that
12 is whether or not the G2 filter could be retrieved?

13 A Yes, sir. So it's a mechanical question.

14 MR. LOPEZ: Okay. Could we have Exhibit 5339,
09:00:28 15 please, Felice.

16 BY MR. LOPEZ:

17 Q Do you have that on your screen, Dr. Parisian?

18 A Yes, sir.

19 Q And what is that?

09:00:40 20 A It's a 510(k) clearance letter for the G2 Recovery filter.

21 Q Is this a document you reviewed in preparation of your
22 testimony here today?

23 A Yes, sir. It would be included in the 510(k) I reviewed.

24 Q And it's included in your expert report?

09:00:56 25 A Yes, sir.

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:00:58 1 MR. LOPEZ: We'd like to offer 5339 into evidence at
2 this time.

3 MR. ROGERS: No objection.

4 THE COURT: Admitted.

09:01:04 5 (Exhibit 5339 admitted.)

6 MR. LOPEZ: May I display, Your Honor?

7 THE WITNESS: You may.

8 BY MR. LOPEZ:

9 Q We looked at one yesterday and I think you said the
09:01:13 10 language is generally the same with all these -- I'm not going
11 to take you through the same language, but the language with
12 respect to the responsibility of the sponsor or the company is
13 the same in this letter as it is in the Recovery letter we
14 went through yesterday?

09:01:31 15 A Yes. There's a basic boilerplate wording that's used by
16 the government for these letters.

17 MR. LOPEZ: Okay. Could we look at page 2, please,
18 Felice. Right there at the very top, just go ahead and
19 highlight or bring up the entire paragraph.

09:01:48 20 BY MR. LOPEZ:

21 Q Dr. Parisian, first sentence there, "Please be advised
22 that FDA's issuance of a substantial equivalence determination
23 does not mean that FDA has made a determination that your
24 device complies with other requirements of the Act or any
09:02:08 25 federal statutes and regulations administered by other federal

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:02:12 1 agencies."

2 What does that mean?

3 A It's basically that the only thing that was used for
4 clearance is substantial equivalence to other devices and it's
09:02:21 5 not to be confused with an approval or some kind of different
6 type of requirement. So the only thing that's cleared here is
7 substantial equivalence based on their representation to the
8 prior devices that have been sold.

9 Q And then the next sentence: "You must comply with all the
09:02:39 10 Act's requirements, including but not limited to:
11 Registration and listing, labeling, good manufacturing
12 practices -- practice requirements," et cetera.

13 Is there any question there that FDA is telling the
14 manufacturer who is getting this clearance that they must
09:02:58 15 comply with those statutes?

16 A No. The wording is it must -- and it's actually the same
17 information that was in that earlier paragraph that we had
18 looked at for the prior 510(k) letter. FDA just kind of
19 reorganized it.

09:03:12 20 So it's saying what your duties are. If you sell a
21 product in the United States, you must comply with, and it
22 gives the list.

23 MR. LOPEZ: And then can we go to page 2, Felice, of
24 this exhibit.

09:03:24 25 I'm sorry, page 3.

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:03:26 1 BY MR. LOPEZ:

2 Q And what is that, Dr. Parisian?

3 A This is really what's cleared. This is the cleared
4 indications for use. So it's saying for 510(k) number

09:03:37 5 K073090. K07 is the year it was filed with the FDA, and the
6 number would be the number in place in terms of when it was
7 filed at the FDA.

8 And so the FDA clears what a manufacturer can market
9 their device legally for the United States.

09:03:56 10 So the 510(k) provides what the indications for use
11 are. The FDA then signs off on whether it's a prescription
12 device, and these are the indications that you can use for
13 marketing your device. So these are the cleared indications.

14 MR. LOPEZ: Felice, could you highlight the last
09:04:13 15 bullet point on this page, please.

16 BY MR. LOPEZ:

17 Q Dr. Parisian, is this what FDA was clearing from this
18 submission, 510(k) submission?

19 A Yes. This was for the Recovery option in terms of
09:04:31 20 recovery. And so they're saying the instructions supplied
21 under this section label. That would be the labeling that the
22 manufacturer has created.

23 Q Did this 510(k) clearance approve, let's use the word
24 "approve," Bard making statements that the this device can be
09:04:52 25 safely removed at any time during the lifetime of the patient?

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:04:56 1 A No. It's basically putting it on the manufacturer that
2 you're required to have an adequate label.

3 So what you want to market it for has to be safe and
4 effective. So it's under the Bard label.

09:05:10 5 Q So it wasn't cleared for that, either, was it? Was it
6 cleared for unlimited retrievability?

7 A No. They didn't ask for that. They just provided the
8 EVEREST data, and they opted to not put any information in the
9 label. Other manufacturers do. This manufacturer didn't.

09:05:29 10 Q What is a 510(k) manufacture's obligations under the
11 federal regulations with respect to updating their labeling?

12 A They can update -- they're required to update their
13 labeling at all times because the 510(k) manufacturer's
14 responsible for insuring the adequacy of their labeling.

09:05:49 15 There's no restriction. The only thing that's restricted is
16 if you make new claims. That has to come back to the FDA.

17 But if you're -- if you have safety information, you
18 can immediately put it in your label.

19 And labeling also includes your sales reps. So you
09:06:04 20 can train your sales reps. Anything you say or do as a
21 manufacturer is considered labeling. And so --

22 MR. ROGERS: Your Honor, I'm sorry to interrupt, but
23 I think we're moving into an area.

24 THE COURT: Overruled. I think she's still
09:06:20 25 responding to the question.

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:06:22 1 THE WITNESS: Right. So in terms of if you're going
2 to market the product in terms of 21 CFR 801.109, which is the
3 labeling, prescription labeling, requirement, it's your
4 continuing duty as you get more human data to put that
09:06:36 5 information in your label so that a physician looking at it
6 will know what the potential benefits and risks are and
7 whether they want to use this device versus something.

8 And labeling would include your marketing, includes
9 your sales reps. Anything that comes from the company about
09:06:51 10 their product.

11 Q I was going to ask you that question. So labeling is not
12 just the IFU?

13 A No.

14 Q Does it entail any communications coming from the company?

09:07:00 15 A Yes.

16 Q Does the Office -- remind -- I have to ask you to do that
17 for me so I'm going to ask you to do that for the jury. What
18 is the Office -- what is ODE?

19 A Office of Device Evaluation. And that's considered a
09:07:21 20 premarket arm of the Center for Devices and Radiological
21 Health. They look at new products manufacturers want to sell.
22 So their job is clearing devices to go to market.

23 Q Can I interrupt and ask you a quick question about that.

24 That is, does that office have post-market oversight on
09:07:40 25 medical devices?

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:07:42 1 A No. That would belong to the Office of Compliance, Office
2 of Surveillance and Biometrics, the district offices.

3 So ODE is involved just with new devices. Compliance
4 is all the post-market issues involved of when products are
09:07:57 5 being sold in the United States.

6 Q The EVEREST study that was included with the application
7 for clearance for retrievability, was that submitted to ODE or
8 to the post-market office?

9 A That would be to ODE because it's requesting a new
09:08:13 10 indication which would be retrieval. That is showing it can
11 be retrieved. That wouldn't have gone to post-market.

12 Q Now, what are the main purposes of the federal regulations
13 as they pertain to the obligations of medical device companies
14 in the design and marketing of those devices?

09:08:32 15 MR. ROGERS: Objection, Your Honor. I believe that's
16 vague and very broad.

17 THE COURT: Overruled.

18 THE WITNESS: The purpose of the FDA is to -- the FDA
19 is the gatekeeper for new products, but the regulations
09:08:45 20 actually apply to the manufacturers' duties to make sure they
21 sell safe and effective products, they continue to sell safe
22 and effective products, that they have mechanisms in place in
23 terms of good manufacturing practices to look at complaints,
24 to do recalls, to communicate with physicians.

09:09:03 25 The companies are required to have people who monitor

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

1 how the product performs, monitor the medical literature.

2 So the thrust of the Act is actually on the
3 manufacturer. The FDA has a small role in it, in implementing
4 what Congress has asked, but the primary regulations apply to
5 the manufacturer.

6 Many devices are now exempted from any kind of
7 interaction with FDA before they're sold. That puts all
8 responsibility primarily on the manufacturer. No premarket
9 notification.

10 Q Is a short way of saying that that the federal regulations
11 impose a duty on manufacturers to protect the rights, health,
12 and safety of consumers?

13 A Yes.

14 MR. LOPEZ: Can I have Exhibit 5340, Felice, please.

15 Page -- well, first of all --

16 BY MR. LOPEZ:

17 Q What is this, Dr. Parisian?

18 A This is a cover page for 510(k) for the Recovery G2 filter
19 and the delivery system, the delivery kits.

20 MR. LOPEZ: Your Honor, we'd like to move 5340 into
21 evidence at this time.

22 MR. ROGERS: No objection.

23 THE COURT: Admitted.

24 (Exhibit 5340 admitted.)

25 MR. LOPEZ: Thank you, Your Honor. I'd like to go to

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

09:10:24 1 page 158. May I display that to the jury, Your Honor?

2 THE COURT: You may.

3 MR. LOPEZ: Could we just have the top portion of
4 that, Felice, highlighted -- I mean made larger.

09:10:47 5 BY MR. LOPEZ:

6 Q And we talked about this yesterday, the Truthful and
7 Accuracy Statement. Again, what is the purpose of the
8 Truthful and Accuracy Statement?

9 A It's to ensure the FDA that -- the reviewer, that you can
09:11:02 10 believe the information that's provided in the 510(k). That
11 the company is certifying -- it has to be a member of the
12 company, not a consultant -- that it's truthful and accurate
13 information and that no material facts are not provided to the
14 FDA.

09:11:17 15 It supports substantial equivalence.

16 Q Now, is the language that is contained within this
17 submission consistent with what you understand this language
18 should read in a submission like this?

19 MR. ROGERS: Objection, Your Honor. Disclosure.

09:11:32 20 THE COURT: Is this addressed in the report?

21 MR. LOPEZ: No, Your Honor.

22 THE COURT: Objection sustained.

23 BY MR. LOPEZ:

24 Q "No material facts for review have been knowingly
09:11:44 25 omitted." That means -- what does that mean exactly? Just

DIRECT EXAMINATION (CONT'D) - SUZANNE PARISIAN, MD

1 tell the jury, what does that mean?

2 MR. ROGERS: Objection, Your Honor. Disclosure.

3 THE COURT: Is that in her report?

4 MR. LOPEZ: It might be, Your Honor. I know we
5 talked -- this was in the report, the Truthful and Accuracy
6 Statement.

7 THE COURT: You can show me where it's addressed?

8 MR. LOPEZ: I'll move on.

9 THE COURT: Okay.

09:12:04 10 BY MR. LOPEZ:

11 Q "Least burdensome." What does that mean? You mentioned
12 that yesterday.

13 A Least burdensome, as described in my report, is from the
14 Food Drug and Modernization Act of 1997. That FDA reviewers
09:12:32 15 are required to use the least burdensome method for industry
16 to get a product on the market. This was put in because
17 Congress felt that it was important to get new products on the
18 market and they wanted to make sure that the FDA didn't use
19 overburdensome requests. So the FDA reviewers are required to
09:12:51 20 make sure they don't ask anything of one manufacturer that
21 they may not have asked of a similar manufacturer unless they
22 have data.

23 So there's restrictions on what the FDA reviewer is
24 allowed to ask, what the FDA in general can ask, and so it has
09:13:07 25 to be what they call least burdensome.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

Q Is there a mechanism for FDA to remove 510(k)
clearanced -- cleared products?

A No. Once you're cleared, you're cleared.

The FDA doesn't go back and review 510(k)s at all.
There's no requirement for coming back and getting a clearance
reviewed in, like, certain times, like three years or
something, to see if it actually works.

So once you're on the market, you're cleared. It's
your device and you keep selling it. And the FDA has no real
interaction other than when you come and ask for a new device,
new 510(k).

Q Whose responsibility is it, therefore, to remove a 510(k)
cleared product?

A The only ones I've seen have been removed by
manufacturers.

MR. LOPEZ: Those are the only questions I have at
this time, Your Honor.

THE COURT: All right.

Redirect.

MR. ROGERS: Thank you, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. ROGERS:

Q Morning, Dr. Parisian.

A Good morning.

Q How are you?

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:14:29 1 A I'm fine. How are you?

2 Q I'm well. Thank you.

3 Doctor, I want to start with something you said
4 yesterday afternoon in your testimony. And I believe you said
09:14:39 5 that the FDA changes. Is that true?

6 A It has to change in terms of technology, yes, sir.

7 Q And am I correct that when you started at FDA that was in
8 1991?

9 A Yes, sir. August 1991.

09:14:54 10 Q Thank you. And I believe you left in 1995.

11 A Yes, sir. August 1995.

12 Q So you were there about four years?

13 A Yes, in the public health service.

14 Q And so when the Recovery filter, the first Bard
09:15:09 15 retrievable filter, when it was cleared by the FDA in 2002,
16 you had been gone from FDA for about seven years?

17 A Yes, sir.

18 Q So when the G2 was cleared in 2005, you had been gone
19 about ten years; is that right?

09:15:26 20 A Yes, sir.

21 Q And would you agree that when the G2X was cleared in 2008,
22 you had been gone about 14 years?

23 A Yes, sir.

24 Q And, likewise, when the Eclipse was cleared in 2010, you
09:15:37 25 had been gone about 15 years?

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:15:40 1 A That's right.

2 Q And, Dr. Parisian, so today is it correct that you've been

3 gone from FDA for about 20 years?

4 A Yes, sir, but I've been engaged in FDA proj- -- issues

09:15:54 5 since then.

6 Q Am I correct that your tenure at FDA had ended before any

7 retrievable filter on the market had ever been cleared?

8 A Right. Only ones I had been involved with there at the

9 FDA were permanent.

09:16:09 10 Q And you are not critical of the FDA; right?

11 A No, sir.

12 Q You aren't critical of the folks that work at FDA?

13 A No, sir.

14 Q And, doctor, since you left FDA in 1995, am I correct that

09:16:21 15 you have worked as a consultant?

16 A Yes, sir.

17 Q I believe you have a consulting business?

18 A Yes, sir.

19 Q It's called Medical Device Assistance; is that right?

09:16:30 20 A At one time. Now it is called MD Assist, Inc.

21 Q That is your sole source of income?

22 A Yes, sir.

23 Q And, so, Doctor, since 1997 when you left FDA, am I

24 correct that you have --

09:16:44 25 A 1995.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:16:46 1 Q I'm sorry. Excuse me.

2 When you left in 1995 that you have traveled
3 throughout the country testifying in courts like we're here
4 today; is that right?

09:16:57 5 A I didn't begin testifying or involved in any litigation
6 until '97, and I was also consulting for manufacturers at that
7 time. So not everything was to do with just testifying. It
8 was involved also with litigation support. Most of my work is
9 done at home looking at documents.

09:17:17 10 Q Fair enough. Would you agree, though, since 1997 you've
11 appeared in large number of courts testifying; is that
12 correct?

13 A I would agree with that.

14 Q Okay?

09:17:26 15 MR. ROGERS: So can we have Exhibit 8483, please.
16 And, Your Honor, I would like to display this for
17 demonstrative purposes only.

18 MR. LOPEZ: Disclosure, Your Honor.

19 THE COURT: Have you shown this to --

09:17:47 20 MR. ROGERS: It's my understanding we have.

21 THE COURT: Have you seen it, Mr. Lopez?

22 MR. LOPEZ: Yes, Your Honor.

23 THE COURT: All right. Overruled.

24 MR. ROGERS: Thank you.

09:17:54 25 THE COURT: Well, do you have any other objection to

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:17:56 1 display --

2 MR. LOPEZ: No, Your Honor.

3 THE COURT: All right.

4 You may display it.

09:18:00 5 BY MR. ROGERS:

6 Q Dr. Parisian, do you see this map?

7 A Yes, sir.

8 Q And would you agree with me that in the states that are
9 shaded in blue, those are states where you have been involved
09:18:09 10 in a case where you have given an expert opinion?

11 A Well, my report may have been. I mean that shading --
12 it's a very pretty chart and I match, but it's my report. So
13 I haven't actually physically been in every one of those
14 states.

09:18:26 15 Q Understand. Fair comment. So even though you haven't
16 actually appeared and testified in each one of these states,
17 you have issued a report in a case pending in every one of
18 these states?

19 A Yes. Related to FDA. And Puerto Rico, don't forget that.

09:18:40 20 Q No, it's down there, the little dot down at the bottom.

21 A So in 20 years, my reports have gone all over most of the
22 country in terms of various cases that I've been involved
23 with.

24 Q And would you agree with me that for your history with
09:18:54 25 giving depositions that you have been deposed at least 237

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:18:58 1 times?

2 A Actually it's 239 now.

3 Q Thank you.

4 A That's 20 years.

09:19:04 5 Q And you are compensated when you give a deposition;
6 correct?

7 A Correct.

8 Q Are you typically compensated by the attorney who retained
9 you?

09:19:13 10 A No. That's unfortunate. It's usually the other side
11 that's questioning me.

12 Q Understand. And would you agree with me that you have
13 testified in court, like you're doing today, at least 90
14 times?

09:19:24 15 A Yes, sir, about the FDA.

16 Q And when you appear in court, would you agree with me that
17 you are compensated by the attorney that retained you?

18 A Yes, sir.

19 Q And, Doctor, am I correct that you have primarily been
09:19:36 20 retained by lawyers who are representing plaintiffs in
21 personal injury cases against drug companies and medical
22 device manufacturers?

23 A Well, I choose my cases. I've accepted defense cases, but
24 they've not resulted in going to court or testifying.

09:19:52 25 Q Okay. Thanks for that answer, but I think I was asking

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:19:56 1 something a little different.

2 Would you agree with me that you've been primarily
3 retained by lawyers representing plaintiffs in personal injury
4 cases against drug companies and medical product companies?

09:20:06 5 A Well, those are the cases I've chosen.

6 Q Okay. But that is who has primarily retained you;
7 correct?

8 A Yes, but those are the ones I select.

9 Q And, Doctor, am I right that you have offered opinions
09:20:19 10 against at least 46 medical device companies?

11 A Yes, sir. And I think 26 drug companies. In 20 years.

12 Q And so you have appeared about a large number of different
13 medical products; correct?

14 A Yes, sir. All about the FDA and how product got on the
09:20:36 15 market.

16 Q And would you agree that you have provided testimony
17 against the manufacturer of a pacemaker?

18 A A pacemaker? Over 20 years?

19 In court or in deposition?

09:20:47 20 Q Either one.

21 A In deposition, yes, sir.

22 Q Okay. And would you agree you have given opinions against
23 the manufacturer of a pain pump?

24 A Various pain pumps that were implanted off label. Yes,
09:20:59 25 sir.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:21:00 1 Q Would you agree you've given opinions against over-counter
2 Motrin?

3 A Yes. For a blind girl. Yes, sir.

4 Q And would you agree you've given opinions against hip
09:21:11 5 implants?

6 A Various hip implants for various patient injuries, yes,
7 sir.

8 Q And you've given opinions against knee implants?

9 A Yes, sir, but, again, it's all FDA.

09:21:20 10 Q And you've given opinions against penile implants?

11 A Yes, sir.

12 Q And you've given --

13 A Inflatable. Inflatable penile implants.

14 Q Thank you. And you've given opinions against insulin
09:21:30 15 pumps?

16 A Implanted insulin pumps and patient deaths, yes, sir.

17 Q And you've given opinions against a flu vaccine?

18 A A woman's nose fell off. Yes, sir.

19 Q And you've given opinions against suture material for
09:21:44 20 surgery?

21 A That was infected, yes, sir, and poorly made.

22 Q And you've given opinions against manufacturers of stomach
23 staplers used in surgery?

24 A Staples came out, yes, sir, and the person died.

09:21:55 25 Q And you've given opinions against manufacturer of contact

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:21:59 1 lenses?

2 A Yes, sir.

3 Q Am I correct you've also given opinions against a
4 manufacturer of an electric wheelchair?

09:22:07 5 A Yes, sir. Patient death.

6 Q And would you agree you've given an opinion against a
7 manufacturer of a spinal cord implant device?

8 A Yes, sir. Patient injuries. It's all FDA.

9 Q And you've given opinions against the manufacturer of a
09:22:23 10 ventilator?

11 A Yes, I did.

12 Q And you've given opinions against the manufacturer of a
13 bone anchor?

14 A Oh. That was an off-label use for a bladder sling. Yes,
09:22:35 15 sir.

16 Q All right. Doctor, you've also given opinions regarding
17 pharmaceutical products or drugs; correct?

18 A Yes, sir. FDA regulated products.

19 Q That would include hormone therapy?

09:22:46 20 A Yes, sir, in breast cancer.

21 Q That would include you've given opinions against the
22 manufacturer of Fosamax?

23 A Yes, sir.

24 Q And that's a product used for osteoporosis?

09:22:56 25 A Yes. Osteonecrosis of the jaw.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

Q And you've given opinions regarding Paxil, an antidepressant?

A Birth defects. Yes, sir.

Q And you've given opinions against asthma drugs?

A Deaths. Yes, sir.

Q And you've given opinions against heparin, which is an anticoagulant; correct?

A That was an unusual case of a contaminated heparin that had come into the United States. Yes, sir.

Q Doctor, I want to spend --

A That's actually more biologic than a device.

Q Okay. Thank you for that clarification.

MR. ROGERS: We can take this down.

BY MR. ROGERS:

Q Doctor, I want to talk to you a little bit now about your compensation for your work.

A Yes, sir.

Q I think we established you started consulting in 1997; right?

A No, I started consulting for industry in 1995. I started consulting in litigation support, actually here in Phoenix, in 1997.

Q Okay. Thank you. And I'm going to start you in the year 2006. Is that okay?

A Okay. I'm not good on times.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:23:56 1 Q I understand.

2 A I'm old.

3 Q Listen, I'm getting older standing right here.

4 But, Doctor, would you agree that in 2006 you made
09:24:06 5 \$600,000 from your litigation consulting?

6 A Yes. And I've given all these numbers up through even
7 until this year. Yes. So you have them available.

8 Q Okay. And you would agree in 2007 you earned
9 approximately \$700,000?

09:24:21 10 A Probably. Yes, sir.

11 Q And in 2008 you earned approximately \$800,000; is that
12 right?

13 A Right. And that would be mixed, manufacturers and
14 testimony, litigation support.

09:24:34 15 Q And so if we add up the 2006 income, 2007 income, 2008
16 income, that would total 2.1 million; is that right?

17 A Right. This is my company. I don't get it all.

18 Q Understand. You pay taxes; right?

19 A Yes, sir, I do pay taxes.

09:24:53 20 Q Doctor, would you agree with me that between 2009 and 2017
21 you earned \$6.4 million working for plaintiffs lawyers?

22 A Yes. At an hourly rate. Yes, sir. So there's a lot of
23 hours there.

24 Q Right. And so if we add the 2.1 million to the
09:25:12 25 6.4 million, would you agree with me that total is

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:25:16 1 \$8.4 million?

2 A You know, I'll trust you. I don't know. You've got the
3 numbers in front of you.

4 Q Okay. And so that was the period from 2006 to 2017.

09:25:27 5 Correct?

6 A Yes, sir.

7 Q And as you've established, you did do some consulting
8 prior to 2006; correct?

9 A Yes, sir.

09:25:34 10 Q And you've done litigation consulting since 2017; right?

11 A Yes, sir.

12 Q So, Doctor, do you think it's a fair estimate to say that
13 you've made over \$10 million from testifying for plaintiffs
14 lawyers in cases against drug companies and medical product
09:25:47 15 companies?

16 A No. I think -- it's the testifying confuses, I think, the
17 jury. I'm talking about sitting in my office looking at
18 documents, tons of documents, going through them, writing
19 reports. That would be litigation support. Having to do
09:26:01 20 depositions, having to defend those. It's not all sitting in
21 court.

22 Then I also work for manufacturers until about three
23 years back, then I stopped because I'm trying to retire.

24 So it's a whole thing. But it's an hourly rate
09:26:15 25 usually sitting here or at my desk doing work.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:26:19 1 Q Thank you for that clarification, Dr. Parisian, but would
2 you agree you made more than \$10 million from litigation
3 consulting, taking into account all of the things you do as
4 part of that?

09:26:30 5 A Over 12 years? Yes. But that would be nothing compared
6 to what I could get in industry.

7 Q Doctor, let's talk a little bit about how you charge for
8 your time.

9 Am I correct that you charge \$600 an hour for
09:26:42 10 reviewing depositions and documents?

11 A This case -- this litigation -- I don't think it's that.
12 I think it's \$400 for review and \$600 to be sitting here
13 today.

14 Q Okay. But you would agree with me that in other
09:27:00 15 litigation currently you're charging \$600 an hour; is that
16 right?

17 A In my post-retirement litigation, yes, sir. I've raised
18 my rates to \$600 an hour.

19 Q And you typically charge \$1,000 an hour for giving
09:27:13 20 deposition testimony or trial testimony; correct?

21 A For any new litigation, yes, sir.

22 Q As I understand it today, I believe you said you were
23 being paid \$600 an hour; is that right?

24 A Yes, sir.

09:27:22 25 Q And Doctor --

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:27:24 1 A And that's the going rate. There's not very many of us.
2 That's the going rate.

3 Q Thank you.

4 I understand you typically charge \$1000 an hour if
09:27:37 5 you have to leave your office; is that right?

6 A Only now for post-retirement cases I'm doing. This would
7 be \$600 an hour to leave my office for this litigation.

8 Q You live here in Phoenix; right?

9 A Yes, I do.

09:27:48 10 Q So you just drove across town to get here?

11 A Yes, sir. But I'm not in my office working on other
12 issues.

13 Q Okay. Let's talk a little bit about your experience just
14 sort of in general.

09:28:02 15 I understood you to say you have a license to
16 practice medicine; is that right?

17 A Yes. In the state of Arizona and state of Virginia.

18 Q And you were a pathologist; is that correct?

19 A Amongst other things. I've been an ER doctor, general
09:28:14 20 practitioner. I'm board certified in anatomic and clinical
21 pathology. I look at myself as a regulatory physician.

22 Q And, Doctor, a pathologist is someone we typically think
23 about who looks at slides and make diagnoses based on what
24 they see; is that right?

09:28:34 25 A No. They also do anatomic pathology, which would be

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:28:38 1 autopsies. So you have the slides. I also ran -- I'm
2 qualified to run a clinical laboratory. Pathologists have
3 evolved. They used to be so ugly, like Jack Klugman, to now
4 where they're very pretty, they know everything.

09:28:52 5 So, yes, various things. What you see on television.
6 All kinds of things.

7 Q And, Doctor, you have not done any work in this case as a
8 pathologist; is that true?

9 A Well, you can't avoid what you know in terms of your
09:29:04 10 medical training and experience. I'm not a pathologist for
11 this litigation. But you're not going to take my knowledge
12 out of my head when I look at things.

13 Q Understand. But you're not offering any opinions in this
14 case regarding Mrs. Hyde specifically or any of her records;
09:29:21 15 correct?

16 A That's correct.

17 Q And, Doctor, you are not a radiologist or an
18 interventional radiologist; correct?

19 A No, but I did that for the FDA as their expert in the
09:29:29 20 radiology branch.

21 Q And you have no hands-on experience implanting inferior
22 vena cava filters; correct?

23 A That's correct.

24 Q And you've never had any involvement with IVC filters when
09:29:40 25 you were at FDA. True?

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:29:43 1 A I don't -- I don't know that that's true because I knew
2 that there was a discussion -- I recall now there was a
3 discussion before 1996 to reclassify them, and so there were
4 actually discussions about the pre-amendment status in that
09:29:56 5 they're Class III and they're going to reclassify them to
6 Class II. But they would have been permanent filters that
7 were placed by surgeons at that time.

8 Q And, Doctor, if you had testified previously that you had
9 no involvement with IVC filters when you were at the FDA, you
09:30:13 10 wouldn't dispute that, would you?

11 A I wouldn't dispute it. I recall I did, but it wasn't
12 hands-on involvement with review of any of these products.

13 Q Okay. Thank you, Doctor.

14 And, Doctor, you never had any experience in your
09:30:26 15 consulting business with IVC filters until you were contacted
16 by Plaintiffs' counsel in this case; is that correct?

17 A Yes, sir. I think those were around 2011 and 2012.

18 Q And you've never designed an IVC filter?

19 A That's correct.

09:30:39 20 Q And you've never tested one?

21 A That's correct.

22 Q And you've never conducted any scientific studies on the
23 forces inside the inferior vena cava, have you?

24 A Right. And FDA reviewers wouldn't do that.

09:30:51 25 Q And you are not an expert in engineering; correct?

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:30:55 1 A I'm not an engineer. I've had to deal with the engineers
2 and engineering issues at the FDA. So I'm -- hands-on
3 training in terms of medical issues and engineering. But I'm
4 not an engineer and I'm not here to describe engineering
09:31:10 5 issues with this case.

6 Q And, Doctor, would you agree that as far as having any
7 real world experience in the design, testing, manufacturing,
8 or bringing to market of an IVC filter, you have not done
9 that?

09:31:21 10 A Not that. That's correct.

11 Q Okay. Thank you.

12 Doctor, let's shift gears a little bit. You
13 testified something yesterday that I wasn't quite clear on. I
14 believe you said at one point you worked for the United States
09:31:35 15 Public Health Service; is that right?

16 A Well, when I was with the FDA I was in the United States
17 Public Health Service. I was assigned to the FDA.

18 Q And did the United States Public Health Service assign you
19 to the FDA?

09:31:50 20 A Yes, sir, they paid my tab.

21 Q And so when you were there at the FDA, were your paychecks
22 coming from the United States Public Health Service or the
23 FDA?

24 A From the military, yes.

09:32:01 25 Q Okay. And that's a different government entity than the

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:32:03 1 FDA; true?

2 A Yes, but they have medical officers assigned to the FDA.

3 Q And I believe when you were working for the United States
4 Public Health Service, the surgeon general would technically
09:32:14 5 be your boss; is that correct?

6 A Yes, sir.

7 MR. ROGERS: Can we bring up Exhibit 7411. Please.

8 7411.

9 BY MR. ROGERS:

09:32:33 10 Q Doctor, do you see that on your screen?

11 A Yes, sir.

12 Q Are you familiar with the surgeon general's call to action
13 to prevent deep vein thrombosis and pulmonary embolism?

14 A I now am, yes, sir.

09:32:46 15 MR. ROGERS: And, Your Honor, I would move that this
16 be admitted into evidence.

17 MR. LOPEZ: No objection, Your Honor.

18 THE COURT: Admitted.

19 (Exhibit 7411 admitted.)

09:32:55 20 MR. ROGERS: May we display?

21 THE COURT: You may.

22 BY MR. ROGERS:

23 Q Doctor, you said you are now familiar with this document;
24 is that correct?

09:33:02 25 A Yes, sir.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

Q And you didn't review this document in the process of preparing your report in this case; is that right?

A I don't believe I did, sir.

Q Okay. And -- but you've read it now; right?

A Yes, sir.

MR. ROGERS: And let's go to page 7, please.

BY MR. ROGERS:

Q And you see that this is a message from the Secretary US Department of Health and Human Services; correct?

A Right. That technically would have been my boss when I was in the Public Health service.

Q Okay. So kind of your boss's boss; is that right?

A Yes, sir.

Q Okay. And you see there in the second paragraph --

MR. ROGERS: Can we pull that out, please?

BY MR. ROGERS:

Q And, Doctor, you would agree with me that here in this paragraph it indicates that there have been -- that there are at least 100,000 deaths that may be directly or indirectly related to DVT and PE in the United States; correct?

A Yes, sir.

Q And you don't disagree with that, do you?

A No. I've seen deaths for both.

Q Okay.

MR. ROGERS: And so can we close that out and bring

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

up the last paragraph on that page.

BY MR. ROGERS:

Q And, Doctor, in this paragraph it reads that "The Surgeon General's call to action represents an opportunity for multiple stakeholders to come together in a coordinated effort to reverse the projected trends and to dramatically reduce the pain and suffering caused by DVT and PE."

Did I read that correctly?

A Yes.

Q Kind of a silly question, Doctor, but you would agree that reducing pain and suffering from DVT and PE would be a good thing; correct?

A Correct. And certain actions were put in place in hospitals to try to reduce post-surgical DVTs and PEs. So, yes, it's an important -- it is a cause of death. So I'm very familiar with it. I would not disagree with that statement.

Q Okay. Are you finished, Doctor?

A Yes, sir.

Q Okay. Thank you.

MR. ROGERS: Can we go to page 9, please.

Looking at the second paragraph, can we pull that out.

BY MR. ROGERS:

Q And, Doctor, here it says this call to action came out of a surgeon general's workshop on DVT and PE held in May 2006;

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:35:11 1 is that correct?

2 A Um-hmm.

3 Q You don't dispute that, do you?

4 A No, sir.

09:35:18 5 MR. ROGERS: And can we now go to -- Scott, I'm going
6 to get you to pull something out.

7 Let me move on. I don't see what I was looking for.

8 Can we go to page 11, please.

9 And let's pull out the second paragraph.

09:35:48 10 BY MR. ROGERS:

11 Q And, Doctor, here the surgeon general says there are few
12 public health problems as serious as DVT/PE, yet these
13 diseases receive so little attention.

14 Would you agree with that?

09:36:07 15 A That they receive little attention? I don't think that's
16 necessarily true. But is their workshop and this is what the
17 issue was that the surgeon general wanted to discuss.

18 DVT's and PE's -- and I'm old. Even in the '70s they
19 were considered an important potential risk of death for
09:36:25 20 patients.

21 Q You don't argue with me that the surgeon general said
22 that; correct?

23 A No. No.

24 Q Okay.

09:36:34 25 MR. ROGERS: Scott, could we highlight the next

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:36:38 1 sentence.

2 BY MR. ROGERS:

3 Q And, Doctor, this reads, "Some estimates suggest that
4 these conditions cause more deaths each year than breast
09:36:43 5 cancer, AIDS, or motor vehicle incidents - illnesses or
6 injuries that are well understood by most Americans."

7 Did I read that correctly?

8 A You read that correctly.

9 Q You don't disagree with that, do you?

09:36:57 10 A The way it's written I do disagree with because DVTs and
11 PEs are often complication of those same issues, motor
12 vehicle, breast cancer and AIDS. So they can be -- you don't
13 come in with a DVT and PE automatically. A lot of these
14 people are at risk. But this is the emphasis they wanted for
09:37:15 15 that meeting.

16 Q Okay. But -- so you disagree with the surgeon general; is
17 that right?

18 A I disagree with that the way it was written.

19 Q Okay. Thank you.

09:37:24 20 MR. ROGERS: Scott, would you pull out the first
21 sentence from the first paragraph.

22 BY MR. ROGERS:

23 Q Doctor, this reads, 'Deep vein thrombosis and pulmonary
24 embolism represent a major health problem exacting a
09:37:44 25 significant human and economic toll on the nation."

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:37:46 1 Do you agree with that?

2 A Yes, sir.

3 Q And, Doctor, would you agree with me that an individual
4 who develops a blood clot in their lungs or in their legs are
09:37:58 5 at a higher risk for developing another clot later on?

6 A Yes.

7 Q All right.

8 MR. ROGERS: So let's go to the next page, please.

9 You see that section called Morbidity, can you pull
09:38:08 10 that out, please.

11 BY MR. ROGERS:

12 Q And, Doctor, here I'm looking at the second sentence that
13 begins, "Roughly." Do you see that?

14 A Yes, sir.

09:38:22 15 Q And that sentence reads, "Roughly 30 percent of those who
16 have a DVT in a given year will suffer from a recurrent
17 episode sometime in the next ten years, with the risk being
18 greatest in the first two years."

19 Did I read that correctly?

09:38:37 20 A Right. And it's 30 percent. So it's not everybody. But
21 there is an increased risk you need to be concerned about, and
22 that's what it's saying.

23 Q You don't disagree with this statement, correct?

24 A No.

09:38:46 25 Q And if we go down --

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:38:48 1 MR. LOPEZ: Your Honor, I know this is admitted, but
2 I'm going to object, it's beyond the scope of why she's here.
3 Her expert opinion.

4 THE COURT: I understand. I understand the
09:38:57 5 objection.

6 What's your response?

7 MR. ROGERS: Your Honor, it's cross-examination.

8 THE COURT: Needs to be within the scope. Confirmed.
9 Or sustained.

09:39:05 10 MR. ROGERS: Okay. Thank you. I will move on, Your
11 Honor.

12 BY MR. ROGERS:

13 Q Doctor, let me ask you a little bit about treatment of DVT
14 and PE. You would agree with me anticoagulants are one of the
09:39:19 15 main tools doctors have to treat those diseases; correct?

16 A The primary treatment is anticoagulants.

17 You're talking about treatment as opposed to
18 preventive, because there's other things that are used for
19 preventive stuff in hospitals. But treatment would be
09:39:32 20 anticoagulant.

21 Q Right. And you would agree with me those drugs have
22 risks; correct?

23 A Yes.

24 MR. LOPEZ: Your Honor, same objection. She's not
09:39:41 25 being offered for that purpose as an expert in this case.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:39:44 1 THE COURT: Hold on. Just a minute.
2 Are you -- is your objection that it's beyond the
3 scope?

4 MR. LOPEZ: Beyond the scope.

09:39:51 5 THE COURT: All right. Let me just re-read the
6 question.

7 Objection sustained.

8 MR. ROGERS: Thank you, Your Honor.

9 BY MR. ROGERS:

09:40:13 10 Q Doctor, when we were talking earlier about some of the
11 testimony that you've given against other medical product
12 manufacturers, am I correct that you have testified in court
13 about anticoagulant medications?

14 A Yes, sir.

09:40:27 15 Q And you've been critical of the manufacturer of Xarelto in
16 those trials; true?

17 A In terms of specific issues. Not just critical of
18 Xarelto. There are specific things in terms of particularly
19 the testing and labeling. So I have testified against
09:40:44 20 Xarelto.

21 Q And you've done that in two different courtrooms in this
22 country; is that right?

23 A I believe so. And I've given depositions and had reports.
24 I think I've also testified against contaminated heparin.
09:40:56 25 That would be another anticoagulant.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:40:59 1 Q Okay, Doctor, let's shift gears and talk about some of the
2 opinions you gave yesterday and today.

3 And a lot of what you talked about was substantial
4 equivalence. Do you recall that?

09:41:08 5 A That's the key here in terms of 510(k). Yes, sir.

6 Q Okay. And that's part of the 510(k) process.

7 A That's right. It's all based on that.

8 Q While you were at the FDA, you did not have primary
9 responsibility for reviewing 510(k) applications; is that
09:41:21 10 correct?

11 A That's true. The medical officers don't get assigned as
12 reviewers. They're consultants. I did review one, as I've
13 testified, one 510(k) when someone was going on vacation and
14 it was a product for organ transplants and solution. But
09:41:40 15 there's just not enough medical officers. There's only ten.
16 So we're not primary reviewers.

17 Q And, Doctor, am I correct that the responsibility for
18 signing off on the clearance letters for 510(k) applications,
19 that was something that was done by the division chief for the
09:41:56 20 ODE; correct?

21 A Right. In terms of -- there's a hierarchy as to who signs
22 off documents at the FDA, and it's usually management. Like
23 most government agencies.

24 Q And the folks who would sign off on these clearance
09:42:10 25 letters for FDA, they would have been senior to you within the

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:42:13 1 organization; correct?

2 A No. No. Not as a chief medical officer. No, sir.

3 Q And if you've testified differently to that, would you
4 disagree?

09:42:23 5 A Well, depends what I testified and what the question was.

6 Q All right. Doctor, am I correct, though, that it really
7 would not be your job to sign clearance letters on 510(k)
8 applications while you were at FDA?

9 A That's right. I wasn't management, I was reviewer.

09:42:39 10 Q Let me follow up with you about one thing you talked about
11 yesterday, and I believe you used the term "piggybacking". Do
12 you remember that?

13 A Yes, sir. It's a way to describe the substantial
14 equivalence process.

09:42:50 15 Q Right. And I believe it's your opinion that based on the
16 first application that would have been made for a Bard
17 retrievable filter and where it was compared against the Simon
18 Nitinol filter, every single filter beyond that is then also
19 compared to the Simon Nitinol filter; is that true?

09:43:07 20 A Because they're all substantially equivalent. The company
21 didn't say anything different --

22 Q Okay.

23 A -- in terms of a permanent filter.

24 Q And you would agree the Simon Nitinol filter was cleared
09:43:16 25 in 1990; correct?

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

09:43:18 1 A 1990? I think it was a little -- okay. It was in the
2 '90s.

3 Q Around there. Right?

4 A It was after they reclassified filters into Class II. I
09:43:30 5 think that was '96.

6 Q And when the Recovery filter was cleared, that application
7 used the Simon Nitinol filter as one of the predicates for the
8 Recovery device; correct?

9 A Used two predicates. One was Simon Nitinol, one was the
09:43:43 10 Greenfield filter.

11 Q And are either of those filters available in the US market
12 today?

13 A Yes. Simon Nitinol is still available and so is
14 Greenfield filter. It's gone through different materials but
09:43:53 15 it's still present.

16 Q So if the jury has heard evidence that the Simon Nitinol
17 filter is not available in the United States today, do you
18 think that's incorrect?

19 A No, because I don't know if it stopped marketing. In
09:44:04 20 terms of internal documents, there was always discussion that
21 they should market that. So it would have been a choice by
22 Bard not to sell it.

23 Q And have you confirmed that the Greenfield filter is still
24 on the market today?

09:44:16 25 A The Greenfield filter is still on the market, but it's

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1 been through different materials in terms of the metals.

2 Q And --

3 A And it's a permanent filter. Both of them.

4 Q And if manufacturer of the Greenfield filter is no longer
5 selling that filter, you don't have any evidence to dispute
6 that, do you?

7 A Nope.

8 Q So, Doctor, when the -- the Recovery filter was cleared in
9 2002; correct?

10 A Yes, sir.

11 Q And then when the Greenfield -- not Greenfield. Excuse
12 me. The G2 filter, when the application for it was submitted,
13 its predicate device was the Recovery filter; correct?

14 A Yes, sir.

15 Q And the Simon Nitinol filter was not a predicate for the
16 G2 filter; correct?

17 A It wasn't listed as a predicate.

18 Q And then when the G2X application was submitted to the
19 FDA, the predicate device for that product was the G2 filter;
20 correct?

21 A That's correct.

22 Q And the Simon Nitinol filter was not the predicate that
23 was submitted to FDA; correct?

24 A Well, the predicate's not submitted. It's not listed.

25 Q Right. But in the application, Simon Nitinol filter was

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not identify as a predicate product to the G2 filter; correct?

A Right, but the Recovery only came because of the Simon Nitinol filter.

Q When the Eclipse filter had its 510(k) application submitted, the predicate device for that product was the G2X filter; correct?

A That's the one the company listed. You only need to list one.

Q And the application for that product did not list the Simon Nitinol filter; correct?

A That's correct.

Q Doctor, you would agree with me the time between when the Simon Nitinol was cleared and when the Eclipse was cleared by the FDA via 510(k) applications, that approximately 20 years elapsed during that time period; true?

A Probably so. We're talking about the '90s to the 2010 period of time.

Q Would you agree with me FDA changed over that time period?

A No. I mean, what part of FDA? There's a lot of FDA. I mean --

Q I'm sorry, Doctor, I was trying to use your words.

You agree the FDA changes; correct?

A Well, FDA, like everything, evolves. Are you talking about the Center for Devices? Center for Drugs?

Q Just in general. You would agree that over the 20-year

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09:46:27 1 period there was some evolvement of the FDA; correct?

2 A If you're talking about devices, they would call it
3 technology creep. There has been some technology creep that
4 the new device are supposed to be better than the older
09:46:41 5 devices.

6 Q Let me ask you a little bit more about substantial
7 equivalence.

8 Would you agree that the FDA has stated in a guidance
9 document that if the risk associated with the new device
09:46:54 10 increases compared the predicate device, FDA can still find
11 the new device substantially equivalent if there are increased
12 benefits with the new device?

13 A Yes, I would agree with that in terms of providing the
14 information to the FDA about the increased risk, what the
09:47:11 15 company has done in order to make sure the risk was better,
16 providing information to the physician. If it's better you
17 have a balance between risk versus benefit. So that's what
18 I'm talking about technology creep but you have to tell the
19 FDA about it in order to get cleared. Particularly if you
09:47:27 20 know the risk is worse.

21 Q And, Doctor, would you agree the FDA has stated in a
22 guidance document regarding 510(k)s that when a new device has
23 technological improvements that are important for public
24 health, we may accept greater uncertainty in an assessment of
09:47:43 25 benefits and risk as compared to the predicate device?

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09:47:47 1 A Yes. We did that particularly in pediatric indications
2 when you're trying to take a pediatric device where there was
3 none. So it's risk versus balance. But it has to be all laid
4 out in the application and in the marketing and the
09:48:00 5 information given to physician about the potential risk.

6 Q So, Doctor, you would agree that the FDA will balance
7 potential new benefits with a new device compared to a
8 predicate device and accept new risk profiles?

9 A If they're informed. See, I mean just to say a device can
09:48:16 10 have increased risk, that's assuming the truthful and accurate
11 statement is correct, that the FDA's being informed, and then
12 they can make a decision about public health and the risk
13 versus benefit. So under certain conditions. It's not just a
14 blanket statement.

09:48:32 15 Q But you agree with that as a concept; correct, Doctor?

16 A As a concept I used it a lot as a clinical officer looking
17 at medical devices. But you have to balance the risk versus
18 the benefit that the people know what they're getting or their
19 physician knows what they're getting.

09:48:48 20 Q Doctor, let me ask you about something else you testified
21 about yesterday. I believe you said the manufacturers like
22 the 510(k) process because it's a faster and cheaper; is that
23 correct?

24 A Well, in terms of the user fee there's a significant
09:49:01 25 difference between a 510(k) and PMA. There's safeguards of

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each. It is cheaper and it is faster. There is a mandatory 90 days for a traditional 510(k) and 30 days for special 510(k). That's not part of the PMA. So it is quicker.

Q Doctor, let's me ask if you and I can have an agreement.

If I ask you a question that's a yes or no question, can you respond with that, or either let me know you can't respond with yes or no?

A Yes, sir, I will.

Q Okay. You will agree to do that; right?

A Yes, sir.

Q Okay. Thank you.

And so, Doctor, would you agree it's really the FDA that decides which regulatory path a product will take and not the manufacturer?

A Primary responsibility goes to the FDA, yes.

Q Doctor, would you agree with me that before the year 2000, IVC filters were classified as a Class III medical device?

A Yes, sir.

Q And Class III medical devices are devices in this country that receive the most regulation; is that correct?

A No, sir. This is a pre-amendments Class III device. And do you want me to explain that?

Q That's okay, Doctor.

Would you agree with me that a Class III medical device receives more regulation than a Class II medical

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09:50:16 1 device?

2 A Not a 510(k) Class III device. We're talking about a PMA
3 Class III device. Totally different.

4 Q Okay. But prior to 2000, IVC filters fell into Class III;
09:50:28 5 is that correct?

6 A They were pre-amendment devices that couldn't be
7 classified as to safety and effectiveness. Yes, sir.

8 Q At some point the FDA decided to do something called
9 down-classifying IVC filters; correct?

09:50:40 10 A They chose to reclassify, and those were the permanent
11 filters, in 1996.

12 Q Okay. And remember our agreement about yes or no. Do you
13 recall that?

14 A Yes, sir. It's hard.

09:50:49 15 Q Thank you. And, Doctor, are you familiar with a
16 memorandum that was written by the FDA about the
17 down-classification of IVC filters from Class III to Class II?

18 A Yes, sir.

19 Q Okay.

09:51:00 20 MR. ROGERS: And can we pull up Exhibit 5877, please.

21 BY MR. ROGERS:

22 Q And, Doctor, do you see what's on the screen there?

23 A Yes, sir.

24 Q And do you recognize this memorandum?

09:51:15 25 A Yes, sir.

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Q And that's an internal memorandum from FDA; is that right?

A Yes, sir.

Q And this is written in 1996; is that right?

A Yes, sir.

Q And does this memorialize the reasons why FDA
down-classified IVC filters from Class III to Class II?

A As a pre-amendment -- as long -- yes. But it's a
pre-amendment Class III which is totally different. So it's
not a PMA Class III.

MR. ROGERS: Your Honor, I move this document in
evidence.

MR. LOPEZ: I object. First of all, it's hearsay and
also beyond the scope of her expert testimony.

THE COURT: What's your response on hearsay?

MR. ROGERS: On hearsay, Your Honor, the exception is
803(8), public record. And as far as scope is concerned,
Dr. Parisian testified extensively about the 510(k) process
and this document directly goes to why IVC filters are in the
classification that they're in and why they go through the
510(k) process.

THE COURT: What is your response on 803(8)?

MR. LOPEZ: Pardon me?

THE COURT: What is your response on 803(8)?

MR. LOPEZ: I don't think he's established this is an
official government document.

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09:52:19 1 THE COURT: Hold on.

2 MR. LOPEZ: Also goes beyond the scope of your motion
3 in limine ruling regarding 510(k) clearances and substantial
4 equivalence. This doesn't address any of that.

09:52:38 5 THE COURT: I don't know what you mean by my motion
6 in limine ruling. What motion are you referring to?

7 MR. LOPEZ: Motion in limine regarding FDA evidence
8 as it must relate to substantial equivalence.

9 THE COURT: I don't know what motion you're referring
09:52:52 10 to. Let's approach and we can talk about it.

11 If you want to stand up, ladies and gentlemen, feel
12 free.

13 (Bench conference as follows:)

14 THE COURT: Mr. Lopez, what motion are you referring
09:53:22 15 to?

16 MR. LOPEZ: Motion regarding FDA evidence in the
17 case. Our *Cisson* motion. The issues about what is relevant
18 with respect to the 510(k) --

19 THE COURT: I don't remember that motion. When was
09:53:33 20 that filed? What motion are you talking about?

21 MR. LOPEZ: It's Docket 12533.

22 THE COURT: So this was not in this trial? Is this a
23 motion in limine from a previous trial?

24 MR. LOPEZ: We did it in this one, too.

09:53:51 25 MS. SMITH: This is a motion in limine --

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09:53:54 1 MR. LOPEZ: I'm sorry, yes. You reference --

2 THE COURT REPORTER: I can't hear Ms. Smith.

3 THE COURT: You've got to talk into the mic,

4 Ms. Smith.

09:54:02 5 Gotta let her in, Mr. Lopez.

6 MR. LOPEZ: I was moving over the wrong way. Sorry.

7 MS. SMITH: So this *Cisson* MIL ruling addresses the

8 scope of what they're allowed to talk about regarding FDA.

9 You limited it to 510(k) clearance for Bard products and

09:54:15 10 then --

11 THE COURT: I don't know what you're referring to.

12 Jeff, do you know what order's been referred to?

13 (The law clerk and Ms. Smith confer.)

14 MR. LOPEZ: There's scope in the --

09:54:36 15 THE COURT: I don't remember addressing this. Show

16 me what portion --

17 MR. LOPEZ: FDA evidence --

18 THE COURT: Okay. So plaintiffs seek to exclude the

19 1996 reclassification memo. That's the one being discussed

09:54:53 20 now.

21 MR. LOPEZ: Right.

22 THE COURT: "The Court cannot included that admission

23 of the reclassification memo will unfairly prejudice

24 plaintiffs." So I denied the motion in limine.

09:55:16 25 MS. SMITH: Maybe it's in the --

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THE COURT: Hold on.

What I said was, "Consistent with the Court's earlier ruling, defendants will be precluded from presenting evidence or argument that the FDA approved," in quotes, "Bard retrievable filters for market or that clearance of the devices under 510(k) review constitutes a finding by the FDA that the filters are," quote, "safe and effective," close quote. "But defendants will not be precluded from presenting evidence of the FDA's 510(k) clearance process and lack of enforcement action against Bard. The motion in limine is denied."

MS. SMITH: Right. So this document goes beyond the scope of that. It doesn't reference -- it's nothing to do with the 510(k) process or substantial equivalence.

THE COURT: You specifically moved to exclude this document in that motion and I denied the motion. It was the FDA's 1996 reclassification memo, and I disagreed and I denied it.

So I --

MS. SMITH: Can we ask you to relook at it? It doesn't -- it doesn't relate to the 510(k) process. It's a memo that was way before Bard even submitted anything regards to how the FDA's thinking about the classification --

THE COURT: So you're rearguing the motion?

MS. SMITH: I suppose so.

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09:56:30 1 THE COURT: I'm going to deny the motion to
2 reconsider.

3 As far as scope is concerned, would you address the
4 scope, please.

09:56:36 5 MR. ROGERS: The scope of her testimony?

6 THE COURT: Yeah. The objection is that the memo is
7 beyond the scope.

8 MR. ROGERS: Yes. And, Your Honor, she talked a lot
9 about the 510(k) process and the reason why IVC filters -- you
09:56:47 10 can -- that the FDA wants you to submit 510(k) process is
11 because it was down-classified. So it goes directly to this.
12 And --

13 THE COURT: Goes directly to what?

14 MR. ROGERS: I'm sorry. Directly to why the IVC
09:57:00 15 filters are in the 510(k) clearance process. And Dr. Parisian
16 testified -- I'm sorry --

17 THE COURT: Well, are you intending with this
18 document as you were doing with the surgeon general report to
19 go through and read various portions --

09:57:16 20 MR. ROGERS: Yes, Your Honor.

21 THE COURT: -- and ask if they're read correctly?

22 That will clearly be beyond the scope.

23 I mean, the fact that it was down-classified I think
24 is relevant, that's how it got into 510(k). But that goes as
09:57:27 25 far as her opinion goes.

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1 All those statements in this document about why the
2 filter's ought to be used and how beneficial they are I think
3 is beyond the scope.

4 MR. ROGERS: Okay.

5 THE COURT: So I'm going to overrule the objection to
6 admission. I've previously admitted it.

7 You can established with the witness it was
8 down-classified to 510(k), but I think to the extent you want
9 to try to use that document to go through and have her agree
10 with various statements the FDA made about filters, it's
11 beyond the scope.

12 MR. ROGERS: Understood, Your Honor. I will limit it
13 to that.

14 THE COURT: Okay.

15 MR. ROGERS: Thank you.

16 (Bench conference concludes.)

17 THE COURT: Thank you. Please be seated.

18 MR. ROGERS: Your Honor, again I move this exhibit
19 into evidence.

20 THE COURT: 5877 is admitted.

21 (Exhibit 5877 admitted.)

22 MR. ROGERS: May we display?

23 THE COURT: By the way, it's admitted under Rule
24 803(8).

25 Yes, you may display it.

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09:58:27 1 BY MR. ROGERS:

2 Q Dr. Parisian, you've seen this document up on your screen;
3 correct?

4 A Yes, sir.

09:58:31 5 Q You would agree with me this is an internal memo of FDA
6 from 1996; is that right?

7 A Yes. Summarizing the history of the IVC filter and why it
8 was called a Class III device and that there would be a future
9 PMA submitted at some later time.

09:58:46 10 Q Okay. And you would agree with me that this memo sets
11 North FDA's reasonings as to why it down-classified IVC
12 filters from Class III to Class II.

13 A Well, it reclassified them. The Safe Medical Device Act
14 of 1990 allowed the FDA to go back and look at devices that
09:59:04 15 were still Class III 510(k)s that would require a PMA. They
16 now had the option to just reclassify them as Class II so they
17 could continue to be cleared as a 510(k).

18 So it's a complicated letter that we really haven't
19 discussed.

09:59:20 20 Q Okay. And, Doctor, you would agree with me that this
21 document is the basis for why IVC filters go through the
22 510(k) clearance process; correct?

23 A And they've always gone through the 510(k) process, but as
24 Class III 510(k)s. Now they're just being made Class II
09:59:38 25 510(k)s.

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09:59:39 1 Q Okay. Thank you for that clarification, Doctor.
2 MR. ROGERS: We can pull this down from the screen.
3 Can we pull up Exhibit 5126, please.
4 Your Honor, may I display this? It's in evidence.
09:59:53 5 THE COURT: Yes, you may.

6 BY MR. ROGERS:

7 Q Doctor, do you see there on the screen the Guidance for
8 Cardiovascular Intravascular Filters 510(k) Submissions?

9 A Yes, sir.

10:00:03 10 Q And you talked about this document on your direct
11 examination --

12 A Yes, sir --

13 Q -- correct?

14 A -- and in my report.

10:00:08 15 Q Okay. Thank you.

16 And would you agree, Doctor, that this is something
17 that FDA would refer to as a special control?

18 A They didn't on this document. When they issued it in
19 -- I would consider it a special control, but they didn't
10:00:25 20 make it officially a special control.

21 Q Okay. And would you agree with me, Doctor, this document
22 sets forth various categories that the FDA expects
23 manufacturers to provide them information when they're
24 submitting a 510(k) application?

10:00:40 25 A It's for the design of the 510(k) application, yes, sir,

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1 and I think it's best -- best thoughts. I don't think they
2 call it special control.

3 Q Okay. Thank you.

4 Doctor, let me ask you about some of your opinions
5 that you've given in this case.

6 Am I correct that you have issued not one report but
7 two reports? Is that true?

8 A For -- for the issue in general or this case?

9 Q About Bard IVC filters.

10 A For Bard IVC filters. Yes, sir.

11 Q And, Doctor, let me first ask you about the Simon Nitinol
12 filter. Am I correct that you do provide certain opinions in
13 your report about the Simon Nitinol filter?

14 A The discussion primarily compares them in the design.

15 Q You would agree with me the Simon Nitinol filter was a
16 permanent only filter.

17 A Yes, sir. It was -- yes, sir.

18 Q Okay. And, Doctor, do you recall discussing a clinical
19 study about the Simon Nitinol filter that's in your report?

20 A I believe it was one in their documentation the company
21 had.

22 Q Right, but you remember discussing that in your report?

23 A Yes, sir.

24 Q Okay. Doctor, in there you talked about some of the
25 results of this clinical study about the Simon Nitinol filter.

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10:02:10 1 Do you recall that?

2 A Yes, sir.

3 Q And would you agree this clinical study --

4 A Are we talking about the company's documents about it or
10:02:17 5 are we talking about a study that was published?

6 Q I'm talking about the thing you referenced in your report.
7 I'd be glad to show it to you.

8 A Thing? Thing? I reference internal company documents and
9 so there are some documents about that. There are some
10:02:31 10 literature that's been published, and so I don't -- just want
11 to clarify.

12 Q Fair enough?

13 MR. ROGERS: Can we pull up Exhibit 8533, please.

14 BY MR. ROGERS:

10:02:41 15 Q And, Doctor, do you recognize your report there?

16 A Yes, sir.

17 MR. ROGERS: And can we go to paragraph 101 on page
18 43 of the report.

19 BY MR. ROGERS:

10:02:58 20 Q Doctor, do you see what I'm talking about there?

21 A Yes, sir.

22 Q This is information you included in your report about a
23 clinical study relating to the Simon Nitinol filter; correct?

24 A Yes, sir.

10:03:07 25 Q And, Doctor, in here would you agree with me that what you

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10:03:10 1 stated in the report, one of the things you state, is that
2 during the clinical study there were two filter migrations
3 observed during this study; is that correct?

4 A Yes. And then subsequent changes were made to the Simon
10:03:23 5 Nitinol to try to address that in terms of the company.

6 Q And does your report indicate that the study was changed
7 because of those migrations; is that correct?

8 A Yes, sir. And some of the labeling. They changed the
9 size -- I won't explain. Go ahead. Do you want me to
10:03:39 10 explain?

11 Q No, that's all right, Doctor. Thank you.

12 And would you agree you state in your report that
13 according to this study the rate of filter migration for the
14 Simon Nitinol filter was .8 percent? Is that correct?

10:03:51 15 A Based on what was occurring at that point in time, before
16 changes, yes.

17 Q And would you agree with me that the rate of recurrent PE
18 identified in this study was 1.9 percent? Is that correct?

19 A Yes.

10:04:04 20 Q All right.

21 MR. ROGERS: And if we go down a little bit, please.
22 Further in that paragraph.

23 MR. LOPEZ: Your Honor, I'm going to object. This is
24 beyond scope of her expert testimony with respect to the
10:04:30 25 submission of the 510(k).

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10:04:32 1 MR. ROGERS: Your Honor, these are opinions she's
2 given in this case and it goes directly to what plaintiffs
3 have told the jury as far as this being a reasonable
4 alternative design.

10:04:40 5 THE COURT: Objection is sustained. It's beyond the
6 scope of direct.

7 MR. ROGERS: All right. Thank you, Your Honor:

8 BY MR. ROGERS:

9 Q Doctor, you talked some about adulteration and misbranded.

10:04:58 10 Do you remember that?

11 A Yes, sir, I used the terms yesterday.

12 Q Let me let you get your water. I don't want to distract
13 you.

14 A Thank you. Little cups so I go through it fast.

10:05:06 15 Okay. Thank you.

16 Q Would you agree that if a manufacturer marketed or sold a
17 product that had not been cleared by the FDA that the product
18 would be adulterated or misbranded?

19 A Yes.

10:05:21 20 MR. ROGERS: Okay. Thank you, Doctor. I have no
21 further questions.

22 THE WITNESS: Thank you.

23 THE COURT: Redirect.

24 MR. LOPEZ: Yes, Your Honor. Thank you.

10:05:48 25 Have to use a bean, Your Honor. May I approach for

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10:05:50 1 one minute?

2 THE COURT: You can approach. You want me to, also?

3 MR. LOPEZ: Please.

4 Unless you let me rule.

10:06:00 5 (Bench conference as follows:)

6 THE COURT: I think this is your first approach, so
7 you're down a bean. Go ahead.

8 MR. LOPEZ: Okay. I'm trying to figure out the -- on
9 the money issue going back to 2011. All the money she's made.
10 I know there's a ruling about other cases and other

11 litigation. I'm trying to think of a way to rehab or cure
12 that by -- she hasn't been working on this case since 2011.

13 THE COURT: You mean when she said she first looked
14 at Bard documents or something like that since 2011?

10:06:44 15 MR. LOPEZ: Yesterday she said 2010, clarified it
16 today 2011, 2012.

17 THE COURT: How long has she been on this case?

18 MR. LOPEZ: I mean it's all intertwined, you know.

19 MR. O'CONNOR: Not since two thousand- --

10:07:00 20 THE COURT: What is your point you want to make to
21 the jury?

22 MR. LOPEZ: Well, you know, that she -- she's been
23 involved in this litigation for a variety of other reasons
24 besides just this case. In other words, she's looked at other
10:07:17 25 aspects of this case which explains why she's made the money

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10:07:19 1 she's made over the last two or three --

2 THE COURT: Well --

3 MR. LOPEZ: -- five or six years.

4 THE COURT: I don't think there was any connection on
10:07:29 5 cross between the dollar amounts that they covered with her
6 and her work on this case. Those were just her income for the
7 years. Not on this case.

8 She did say she started work on this in 2011.

9 MR. LOPEZ: Right. But --

10:07:48 10 THE COURT: Go ahead.

11 MR. LOPEZ: I'm sorry. Didn't mean to interrupt you.
12 But the issue is always the scope of what that applies to.

13 So if she spent that much time and money and billed
14 that much money on this case, I would think we have the right
10:08:05 15 to explain to the jury why. I mean he has -- the state thing
16 he put on, about 18 of those states involve IVC filters. He
17 put the map up and I don't know -- he didn't specifically say
18 this was this drug, this drug, this drug. I want to be able
19 to say --

10:08:28 20 THE COURT: Tell me what it is you want to do. What
21 do you think you want to ask her?

22 MR. LOPEZ: I want to be able to say you qualified in
23 those states that Mr. Rogers put up, those 45, how many of
24 those states did you qualify as an expert to testify about IVC
10:08:39 25 filters. I mean --

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10:08:44 1 MR. ROGERS: I don't think that's fair.

2 THE COURT: How many of those cases are against Bard?
3 Are they all against Bard?

4 MR. LOPEZ: No, no, no. At least I'm guessing. Let
10:08:55 5 me guess -- she can probably tell, but she's still an expert
6 and doing depositions in probably ten cases.

7 THE COURT: Well, there's been testimony about how
8 much she makes in general, not tied to any specific case and
9 certainly not tied to this case.

10:09:13 10 It seems to me the only concern you're expressing
11 about prejudice to you in this case is her statement that
12 she's been working since 2011; is that right?

13 MR. LOPEZ: That's one. But also the -- all the
14 states she's -- I mean, can I at least ask her, have you
10:09:30 15 qualified as an expert with respect to IVC filters and federal
16 regulations without mentioning Bard? Maybe the jury knows
17 there's other IVC filter litigation in 11 or 12 of these
18 states.

19 I mean, I didn't put up the map, you did.

10:09:47 20 THE COURT: Hold on.

21 Mr. O'Connor, you want to say something?

22 MR. O'CONNOR: What I want to say is I was sitting
23 there listening to it and he went into 2011. Right now this
24 jury is under the impression --

10:09:58 25 THE COURT: He did not bring up her involvement in

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10:10:00 1 this case in 2011.

2 MR. O'CONNOR: In Bard cases.

3 THE COURT: No. He asked when did you start working
4 on this case or when did you see the first document, and she
10:10:08 5 said 2011.

6 MR. ROGERS: That was on direct yesterday. I did not
7 ask that question.

8 THE COURT: I know she said it. I don't know when
9 she said it. But I don't think he tied her to 2011 in this
10:10:18 10 case.

11 So what do you want?

12 MR. LOPEZ: I want to be able to ask how many of
13 those states that Mr. Rogers put up did she qualify as an
14 expert witness to testify on federal regulations and
10:10:35 15 regulatory issues as involves IVC filters and 510(k)
16 clearances.

17 THE COURT: And do you agree that if you ask that
18 question and she says, "I've given opinions in 18 states on
19 the problems with IVC filters," the jury will clearly infer
10:10:56 20 that Bard has been sued in 18 states on IVC filters?

21 MR. LOPEZ: Well, I didn't put up the map, Judge.

22 THE COURT: I know you didn't. Do you agree with me
23 that will be the inference they're likely to draw?

24 MR. LOPEZ: They've heard Cook, they know there's six
10:11:11 25 or seven -- well, probably.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

10:11:13 1 THE COURT: So the question in my mind is what's more
2 prejudicial? For her to have had -- for you to have had the
3 map shown where she's clearly testified on lots of other
4 stuff, or for the jury to be told, in effect, Bard's been sued
10:11:26 5 in 18 states? I think that's what I'm balancing.

6 MR. LOPEZ: Or maybe for me to be able, you know,
7 show that she's actually qualified and been allowed to testify
8 as an expert on the very issues she's testifying to in this
9 case. Not on a Xarelto case.

10:11:43 10 THE COURT: That doesn't go to the money issue.

11 MR. LOPEZ: It doesn't. This is plaintiffs' subpart
12 B about whether or not she can talk about other cases without
13 mentioning Bard.

14 THE COURT: I understand your position.

10:11:57 15 What's your response?

16 MR. ROGERS: Your Honor, I think that would be highly
17 prejudicial. As you pointed out, on direct Mr. Lopez elicited
18 yesterday that she had been involved in these cases since
19 2010. I thought that was prejudicial, but really wasn't
10:12:13 20 anything I could do about it.

21 As Your Honor pointed out, my questions did not ask
22 her anything about how much she made from IVC filter
23 litigation. I didn't ask her about any invoices. I mean, it
24 was all generalities about how much she's earned and how much
10:12:26 25 she's testified.

CROSS-EXAMINATION - SUZANNE PARISIAN, MD

1 I think to allow that question would be highly
2 prejudicial and way beyond the scope of what I asked.

3 THE COURT: Well, here's my conclusion. As far as
4 the amount she's been paid in her career, I don't think that's
5 been tied to Bard and I don't think there needs to be a
6 clarification to counter that suggestion because I don't think
7 it was given.

8 As far as the number of states that were displayed on
9 the map, Mr. Rogers, without objection, went through a very
10 long list of products and drugs that she's testified about, so
11 I don't think it's a surprise to the jury she's done that
12 around the country. So I don't think the map in itself gives
13 an inaccurate view of the scope of her expert testimony.

14 As far as your ability to bring out that she has
15 qualified as an expert on IVC filters in other states,
16 presumably that would be to rehabilitate her as an expert on
17 IVC filters. I'm assuming that's why you want to do it?

18 MR. LOPEZ: I mean, that's one reason. He's trying
19 to make it look like she's have gun will travel.

20 THE COURT: She what?

21 MR. LOPEZ: Well, that she's just -- I said "have gun
22 will travel." That's a old reference to an old TV show. But
23 that she's traveling around the country on all kinds of
24 things.

25 THE COURT: He has clearly given that implication.

REDIRECT EXAMINATION - SUZANNE PARISIAN, MD

10:13:59 1 But I don't see how the fact that she's qualified as an expert
2 in 18 states on IVC filters counters that. I mean, that --

3 MR. LOPEZ: I can approach it a different way.

4 THE COURT: Okay.

10:14:11 5 MR. LOPEZ: Approach it a different way.

6 THE COURT: Okay.

7 (Bench conference concludes.)

8 THE COURT: Thank you, ladies and gentlemen.

9 MR. LOPEZ: Okay.

10:14:33 10 R E D I R E C T E X A M I N A T I O N

11 BY MR. LOPEZ:

12 Q Well, that map that Mr. Rogers put up, I don't know, there
13 was a few states that were not colored in. I counted about 45
14 states, is that what you saw?

10:14:47 15 A Right. I haven't gone physically to all those states.

16 Q Understand. But have you qualified to testify in those 45
17 states as an expert witness on regulatory issues like you've
18 been qualified to testify in this case?

19 A Yes. And Puerto Rico.

10:15:05 20 Q Oh, I forgot about Puerto Rico.

21 Also, the prior opinions that you rendered before
22 Mr. Rogers got up, were those opinions to a reasonable degree
23 of regulatory and medical certainty?

24 A Yes, sir.

10:15:23 25 MR. ROGERS: Objection, Your Honor. Exceeds the

REDIRECT EXAMINATION - SUZANNE PARISIAN, MD

10:15:24 1 scope.

2 THE COURT: Overruled.

3 BY MR. LOPEZ:

4 Q Now, you also -- as Mr. Rogers was mentioning a lot of
10:15:43 5 these other cases that you were involved in, did some of those
6 lawsuits actually bring to bear some issues that have not been
7 previously known by some of those products?

8 A Yes.

9 Q And how was it that things that were not previously known
10:16:03 10 were revealed by way of litigation in those other cases?

11 MR. ROGERS: Objection, Your Honor --

12 THE WITNESS: Will there was --

13 MR. ROGERS: -- relevance.

14 THE COURT: Hold on just a minute.

10:16:13 15 MR. ROGERS: Relevance, Your Honor.

16 THE COURT: Overruled.

17 THE WITNESS: There's new information that came about
18 when the product was used in human beings or new issues --
19 because the FDA process doesn't get to find out everything
10:16:26 20 that's going to happen when you use a product on people. As
21 soon as you start using products on more people, more things
22 pop up. And so companies have to respond to them.

23 And so most of these cases we're dealing with new
24 issues that may not have been seen in the clinical trials or
10:16:41 25 the clearance application or it's just people -- the more

REDIRECT EXAMINATION - SUZANNE PARISIAN, MD

1 people you add, the more things that actually could start
2 appearing that don't appear frequently enough to come up in
3 the application.

4 Q So how many in those cases you've mentioned in the 20-plus
10:16:58 5 years you've been doing this, how many of those cases, you can
6 give us a percentage, were safety issues revealed only because
7 you and others had an opportunity to look at internal
8 corporate documents?

9 MR. ROGERS: Objection, Your Honor. Exceeds the
10:17:17 10 scope of the *Daubert* order in areas of expertise.

11 THE COURT: Overruled.

12 THE WITNESS: Well just like occurs with the FDA.
13 Those -- most of those cases actually were new safety issues.
14 I'd say almost 99 percent of them.

10:17:37 15 BY MR. LOPEZ:

16 Q No. My question was how many of those safety issues only
17 became public because of your and others --

18 A Right. About 99 --

19 Q -- having reviewed internal corporate documents as part of
10:17:51 20 a lawsuit?

21 A 99 percent. And oftentimes I was also working with FDA
22 documents where the issue had been identified even at the FDA.
23 Those were almost all new issues.

24 Q And Mr. Rogers also asked you questions about your lack of
10:18:06 25 involvement and testimony about safety issues as they relate

REDIRECT EXAMINATION - SUZANNE PARISIAN, MD

1 to IVC filters. Do you remember that?

2 A Yes.

3 Q And when was it that you first became aware that there
4 actually were safety issues and regulatory issues as they
5 relate to Bard IVC filters?

6 A Probably around 2011. I was aware of the FDA's release in
7 2010. Bard specifically, around 2011.

8 Q What did you have to see before you realized that there
9 was some safety issues and regulatory issues as relates to
10 Bard products?

11 A I had to look at corporate documents. I had to look at
12 also the medical literature. I had to look -- so I had to do
13 a search of other things that were available.

14 Q Information and documents that were not in the public
15 domain?

16 A Right. I wouldn't have confidential documents other than
17 from litigation.

18 Q Was it also information and documents that was not in any
19 FDA material that you reviewed from the FDA production?

20 A Right. The FDA doesn't get those documents. The FDA only
21 gets limited documents.

22 Q You had a sign -- you had to agree to a confidentiality
23 even in your role as an expert witness in this case to --
24 having looked at all those documents; correct?

25 A Correct.

REDIRECT EXAMINATION - SUZANNE PARISIAN, MD

10:19:24 1 Q And you're not allowed to talk about those documents
2 outside of this courtroom; isn't that correct?

3 A Correct.

4 MR. LOPEZ: Those are all the questions I have at
10:19:31 5 this time, Your Honor.

6 THE COURT: Okay. You can step down.

7 THE WITNESS: Thank you, Your Honor.

8 MS. REED ZAIC: Next witnesses will be appearing by
9 videotape, William Kuo, MD.

10:20:01 10 Dr. Kuo is a practicing interventional radiologist at
11 Stanford Hospital in California. In 2010 Dr. Kuo established
12 the Stanford IVC Filter Clinic.

13 (Video testimony of Dr. William Kuo played.)

14 THE COURT: Let's pause the video.

10:34:02 15 Ladies and gentlemen, we'll break until ten minutes
16 to the hour. We'll excuse you at this time.

17 (Recess taken from 10:34 to 10:49.)

18 THE COURT: Thank you. Please be seated.

19 All right, let's continue with Dr. Kuo's video.

10:51:14 20 (Video testimony of Dr. William Kuo resumed.)

21 MS. REED ZAIC: Your Honor, that concludes the video.

22 I just wanted to put on the record there were no
23 exhibits moved in.

24 The parties have an agreement. We have a dispute on
11:08:48 25 a few. We'll work them out and address them with the Court at

DIRECT EXAMINATION - MARK HYDE

1 a later time.

2 THE COURT: All right.

3 MR. LOPEZ: Thank you.

4 MS. SMITH: Plaintiffs would like to call their next
5 witness: Mark Hyde.

6 THE COURTROOM DEPUTY: Mr. Hyde, if you'll please
7 stand right here and raise your right hand.

8 **MARK HYDE,**

9 called as a witness herein, after having been first duly sworn
10 or affirmed, was examined and testified as follows:

11 D I R E C T E X A M I N A T I O N

12 BY MS. SMITH:

13 Q Good morning. Can you introduce yourself to the jury.

14 A Yes.

15 Good morning. My name is Mark Hyde.

16 Q And what is your relationship to Lisa Hyde?

17 A I'm Lisa's husband.

18 Q Do you and Lisa have any children?

19 A Yes. We have three children: Nate, Kate, and Grace.

20 MS. SMITH: Felice, could you pull up demonstrative
21 4905.

22 BY MS. SMITH:

23 Q Is this is photo of your family?

24 A No.

25 Q Oh.

DIRECT EXAMINATION - MARK HYDE

11:10:21 1 MS. SMITH: 4905.

2 THE WITNESS: Yes, it is.

3 MS. SMITH: Your Honor, may I display for
4 demonstrative purposes?

11:10:31 5 THE COURT: Any objection?

6 MR. CONDO: No objection.

7 THE COURT: Yes, you may.

8 BY MS. SMITH:

9 Q Now, can you tell us in the photo -- can you identify your
11:10:36 10 children.

11 A Sure. In the bottom photo, bottom left, is my daughter
12 Katelyn. She's the middle daughter. She lives in Milwaukee.
13 She attends school and she also works a couple jobs. We're in
14 contact frequently. Asking for fatherly advice, which I
11:10:59 15 gladly give.

16 Next to her is my son Nate. Nate's 27. Lives in
17 Guntersville, Alabama. He -- last Christmas he was engaged to
18 the woman next to him, Megan. They're getting married in
19 June.

11:11:16 20 Nate and I, we talk everyday. We just have a special
21 relationship. He's -- we talk sports, we talk -- anything and
22 everything. We're very close.

23 And across from Megan is Grace. Bottom picture.

24 That's my youngest and my overachiever. Grace is 16 years
11:11:42 25 old. She'll graduate in two years with an associates degree.

DIRECT EXAMINATION - MARK HYDE

11:11:47 1 She's very special. She's very intelligent, musical, and we
2 obviously have a tremendous relationship.

3 Q And you haven't been here all week; is that right?

4 A That's correct.

11:12:02 5 Q Can you tell us why.

6 A Grace is 16, but she doesn't have a driver's license. In
7 fact she doesn't own a driver's license right now. Thank you,
8 Lord.

9 Grace -- like I said, she's very active. So I had
11:12:17 10 to -- I had to get her around, and I didn't have anybody at
11 the time to help me out with that. So I did fly in this week.
12 My daughter Katelyn came down to help me out so I could be
13 here with you, and next week my son's coming in, flying in, so
14 I can also be here next week. So I apologize for the first
11:12:37 15 week.

16 Q And you and Lisa, how did you meet?

17 A Lisa's good friend and my good friend are brother and
18 sister. So over the years we spent -- we've been to a number
19 of social events together and eventually, through those social
11:12:56 20 events, we got to know each other and started dating.

21 Q And after getting to know Lisa, what was it that attracted
22 you to her?

23 A Well, initially it was a physical attraction, of course.

24 We started dating and soon after I started dating Lisa, it was
11:13:12 25 evident that I wanted to be with her the rest of my life.

DIRECT EXAMINATION - MARK HYDE

1 She's just the most caring person. She is honest.
2 Incredible integrity. We share Christian values. And most of
3 all, she's got an unbelievable relationship with my family,
4 with my kids, who are now our kids.

5 Q Mark, can you tell us a little bit about yourself and your
6 background?

7 A Sure.

8 Well, I'm a veteran. I was in the Army in 1974 to
9 '76, so it was the end of Vietnam. I was honorably
10 discharged.

11 When I came out I became a public safety officer,
12 which probably requires a little bit of explanation. Public
13 safety officer is all three facets of first responders. So I
14 was a policeman, a fireman, and EMT, all certified and
15 registered.

16 During that time I was going to night school and I
17 had a friend, somebody that I just met in school and we would
18 go out and solve the world problems after class, and he told
19 me to go take the air-traffic controllers test, because he was
20 an air traffic controller, which at the time I had no interest
21 in because I had a career and enjoyed it. But he talked me
22 into it, so I did it, and scored very high. And that was in
23 June of 1981. October of 1981 I was hired. And 32 years
24 later I retired.

25 Q And what brought you to Las Vegas?

DIRECT EXAMINATION - MARK HYDE

11:14:49 1 A I was working at O'Hare Tower at the time, I was the
2 operations manager at O'Hare Tower, and an opportunity came
3 about to be to -- to manage a large project out west. It was
4 in Las Vegas but entailed more than Las Vegas. It was an air
11:15:03 5 space redesign project, and they asked me to manage it.
6 Except they needed me there in January of 2011. I accepted
7 the position for career advancement purposes and, in agreement
8 with the family, I moved in January of 2011 knowing they were
9 going to follow in August.

11:15:21 10 Q All right. And so since you've retired, tell us about
11 some activities that you do or enjoy now.

12 A Well, since retirement, I volunteer a lot in Las Vegas.
13 Volunteer at a rescue mission, summer theater. Different
14 things. But most recently, Lisa and I became very involved
11:15:43 15 volunteering together at the Assistance League of Las Vegas.

16 I don't know if anybody knows what the Assistance
17 League is, but it's probably the best charitable organization
18 I've ever seen. We help disadvantaged children. It's
19 incredibly valuable to the community and we're both very
11:16:01 20 active. In fact, Lisa's a director of one of the programs.

21 Q Now I'd like to discuss back in 2003 -- sorry, 2011 when
22 Lisa experienced a PE. When did you find out that Lisa's
23 doctors had recommended that she needed to receive an IVC
24 filter?

11:16:23 25 A I was in -- I was in Las Vegas working at the time and I

DIRECT EXAMINATION - MARK HYDE

11:16:26 1 got a call from Lisa that she was at the emergency room and
2 had a pulmonary embolism. So I arranged a flight immediately.
3 My employer very -- they said take your time, do whatever you
4 need, you got it.

11:16:45 5 I immediately came home. That evening I was in the
6 hospital room with her.

7 Q And did you meet with the doctor the next day?

8 A Yes. Dr. Henry. We met with Dr. Henry in the morning.
9 He discussed -- talked about IVC filter. I never heard of one
11:17:01 10 before. Didn't know what it was. We were -- Lisa was
11 obviously in distress because she had pulmonary embolism.

12 We discussed it. It appeared -- it sounded to me
13 like it was something that was going to help her and something
14 that was going to ease our mind in case the blood thinners
11:17:20 15 didn't work, so --

16 Q And let's move forward to 2014. So Lisa has her filter
17 implanted. When did you first learn of any problems with the
18 filter?

19 A Lisa -- I was at work again, and Lisa called me, which is
11:17:38 20 really unusual. Lisa didn't call me at work. So I knew
21 something was serious. And I could tell by the tone. She was
22 distressed. You know, she explained what they had found, that
23 the filter had fractured. So, again, I immediately went home.
24 Told my employer again I'll be back when I can, and I went
11:18:01 25 home.

DIRECT EXAMINATION - MARK HYDE

11:18:02 1 Q All right. And so after finding out this extraordinary
2 news, what did you guys do next?

3 A Well, we started -- Lisa and I started researching the
4 effects of a fractured filter. I continued when I got home.

11:18:17 5 Obviously we knew we had to go see -- find a cardiologist.
6 She had also found Dr. Kuo on line. So we started to make
7 appointments.

8 Q And do you recall the first appointment that you made?
9 Did you see --

11:18:34 10 A I'm sorry --

11 Q You saw a cardiologist? Dr.--

12 A Yes, Dr. Shehane. We made an appointment to see
13 Dr. Shehane.

14 Q At that appointment do you recall any advice or
11:18:45 15 recommendations that Shehane gave you and Lisa?

16 MR. CONDO: Objection, Your Honor. Hearsay.

17 BY MS. SMITH:

18 Q Can you tell me what you learned from Dr. Shehane at that
19 appointment.

11:18:59 20 A Dr. Shehane advised that he was going --

21 MR. CONDO: Hearsay response.

22 THE COURT: What's your response on hearsay,
23 Ms. Smith?

24 MS. SMITH: I think it's not hearsay, it's his
11:19:14 25 response of what he learned, what he recalled, his memory of

DIRECT EXAMINATION - MARK HYDE

1 hearing advice from Dr. Shehane.

2 THE COURT: Well, the answer was going to recount
3 what Dr. Shehane said to him.

4 MS. SMITH: I'll rephrase it.

5 BY MS. SMITH:

6 Q Did you have an understanding of what Dr. Shehane
7 recommended at that appointment?

8 A Did I have an understanding?

9 Q What was your understanding of his recommendation?

10 A His recommendation was not to elevate her heart rate.

11 Q And did you talk to him about a trip that you were going
12 to take to Wisconsin?

13 A That was the second appointment. It was a follow-up
14 appointment after he instructed us that --

15 MR. CONDO: Your Honor, again, we're moving into
16 hearsay.

17 THE COURT: Sustained.

18 BY MS. SMITH:

19 Q And the trip that you took to Wisconsin, did you make any
20 changes to the trip based on different information you had
21 learned from your doctors?

22 A Yes. I was -- we were instructed that if the filter
23 penetrated the heart, that it was a serious event and she --
24 she would know when it happened and she would have to get to a
25 hospital immediately. So I arranged the trip so that we would

DIRECT EXAMINATION - MARK HYDE

11:20:38 1 be -- stay at bigger cities where large hospitals were
2 available readily. I also knew that she was not going to be
3 alone and I wasn't going to allow her to be alone at any time,
4 and also not do anything that was going to elevate her heart
11:20:56 5 rate.

6 Q And tell me how it felt to plan a trip where you were
7 planning it around a medical condition. How did this make you
8 feel?

9 A It was anxious. It was -- it wasn't a normal family
11:21:09 10 vacation. Our 12-year-old daughter was with us, Grace. It
11 was stressful. Lisa felt that it was -- she was going
12 possibly saying goodbye for the last time to some people. It
13 was hard.

14 Q And a few weeks later and you and Lisa drove to Stanford
11:21:28 15 for your appointment for Dr. Kuo; is that correct?

16 A That's correct.

17 Q Why did you decide to drive instead of fly?

18 A Being an air-traffic controller, flying is -- first of
19 all, Lisa's an anxious flyer. Everybody knows flying over the
11:21:47 20 mountains you get turbulence. Turbulence combined with an
21 uneasy flyer you're going to elevate the heart rate. It just
22 did not seem like a good option.

23 The -- and people think an airplane can just fall out
24 of the sky. It doesn't happen. It takes quite a bit of time
11:22:05 25 if an emergency is declared to get the aircraft on the ground.

DIRECT EXAMINATION - MARK HYDE

1 I just thought the best option was driving.

2 Q And did you have to take off work to attend the
3 appointment with her?

4 A Yes, it was open ended. I think I was out a week to ten
5 days. My employer said you take whatever time you need. They
6 knew it was an emergency situation.

7 Q And how was that drive to Stanford?

8 A It was quiet. I think Lisa probably slept most of the
9 time. It was -- it was like a business trip. I mean it was
10 all business. We were there for a mission. We were there to
11 get this thing that was affecting our lives out of her.

12 Q And so you arrive at Stanford. Do you meet with Dr. Kuo?

13 A Yes, we met with Dr. Kuo and his staff.

14 Q And did Dr. Kuo ask Lisa about any symptoms?

15 A Yes. Lisa -- Lisa went through her symptoms, all the
16 symptoms, and Dr. Kuo indicated, or his staff indicated, that
17 it made sense; those are the things that would happen with the
18 filter the way -- and the shape it was in.

19 Q And while Lisa was in the procedure, what did you do?

20 A I was very nervous. It was -- Stanford's a beautiful
21 campus. I took a long walk, like a two-hour walk. Said a lot
22 of prayers. I was scared. I was considering the worst case
23 scenario. I was afraid that I had to explain to my kids,
24 especially Grace, that the best player on my team was going to
25 be missing. So it was hard. It was very hard. Very

DIRECT EXAMINATION - MARK HYDE

11:23:51 1 difficult.

2 Q And so after the procedure did you meet with Dr. Kuo?

3 A I came back and went to the waiting room and I saw Dr. Kuo
4 walking down the aisle. It was supposed to be like a

11:24:04 5 five-hour procedure and this was after about two, two and a
6 half hours. I thought this is unusual.

7 But when he came to me and he said Lisa's in recovery
8 and doing good. I have to say that -- I'm going to relate an
9 experience. So when I was a fireman, I was fighting a fire in
11:24:26 10 a basement and my air tank went off.

11 MR. CONDO: Your Honor, can we proceed by question
12 and answer, please?

13 THE COURT: Yes, we should.

14 MR. CONDO: Thank you.

11:24:36 15 BY MS. SMITH:

16 Q Mr. Hyde, was it a big relief to hear this news from
17 Dr. Kuo.

18 A Yes. Biggest relief of my life. I was going to relay a
19 story on that, but that's okay.

11:24:47 20 Q And I imagine after this you guys were ready to get back
21 home.

22 A I think --

23 Q What was life like once she returned home?

24 A I think psychologically I just wanted to return back to
11:24:59 25 the way things were. I mean I just -- I couldn't wait to get

DIRECT EXAMINATION - LISA HYDE

11:25:02 1 home. We drove immediately -- my daughter's second day of
2 school, she had her -- it was her open house and we made it
3 back for it, which is great. And it was -- it was good.
4 There was a relief.

11:25:22 5 Q And since she's been back, how has Lisa been?

6 A She's -- she has a lot of anxiety still. There's -- she
7 doesn't sleep well. She wakes up at night. It's -- I think
8 the filter's physically removed but mentally maybe not.

9 Q And how's this affected you?

11:25:46 10 A I'm concerned for her. I'm worried also. I mean I'm
11 happy it's gone, happy it's out, I'm happy we moved on, but
12 there's still effects and issues, and obviously I'm concerned.
13 This was -- this was -- this was -- we have a very strong
14 family. We are very family oriented. This was a key player
11:26:08 15 we almost lost and -- just learn to enjoy every day.

16 Q All right. Thank you.

17 THE COURT: Cross-examination.

18 MR. CONDO: We thank Mr. Hyde but have no questions
19 for him.

11:26:22 20 THE COURT: Okay. Thank you.

21 THE WITNESS: Thank you.

22 MR. O'CONNOR: Your Honor, at this time we would call
23 Lisa Hyde.

24

25

DIRECT EXAMINATION - LISA HYDE

11:27:06 1 **LISA HYDE,**
2 called as a witness herein, after having been first duly sworn
3 or affirmed, was examined and testified as follows:
4 D I R E C T E X A M I N A T I O N
11:27:14 5 BY MR. O'CONNOR:
6 Q Would you introduce yourself to the members of the jury,
7 please.
8 A Yes.
9 Hi. Can you hear me?
11:27:22 10 Okay. I'm Lisa Hyde.
11 Q How are you feeling right now?
12 A Nervous.
13 Q All right. Lisa, we heard from your husband Mark Hyde.
14 Can you tell us how long you've been married?
11:27:36 15 A We've been married 21 years.
16 Q And your children, what are their names and ages?
17 A Nate is 27, Katelyn 25, and Grace 16.
18 Q Tell us about -- just give us some background about you.
19 You lived in Wisconsin and moved to Las Vegas; is that right?
11:27:55 20 A That's correct.
21 Q What were you doing about the time that you met Mark?
22 Were you working?
23 A I was working, yes. I was managing --
24 Q What type of work did you do?
11:28:05 25 A Assistant manager at a jewelry store.

DIRECT EXAMINATION - LISA HYDE

11:28:08 1 Q When you met Mark can you tell us what drew you two
2 together?

3 A We met through mutual friends and got to know each other.
4 I found out his children were adopted. And that was important
11:28:18 5 to me. I'm adopted. So we sort of had kind of a bond. We
6 had this adopted club.

7 Q So did you eventually get together and get married?

8 A Yes.

9 Q And did you become a stepmother?

11:28:32 10 A Yes.

11 Q And that would be to Nathaniel and Katelyn?

12 A Correct.

13 Q And eventually did you and Mark have another baby?

14 A We did. We had Grace together in 2002.

11:28:44 15 Q And how did that all work out bringing a new one into the
16 family?

17 A Well, she wasn't in the adopted club, but -- the kids
18 asked me when I was pregnant with her will Grace be our half
19 sister or stepsister? How does that work? I said, no, she
11:29:02 20 will be your sister. I don't do halves. We're a family.

21 Q And so how does the family get along now?

22 A We get along very well. Very close.

23 Q Let's just move up in time and I want to talk about how
24 you came about receiving your Bard filter. Okay?

11:29:25 25 A Okay.

DIRECT EXAMINATION - LISA HYDE

11:29:26 1 Q And that takes us to about February of 2011; right?

2 A Correct.

3 Q What was going on with you at that time?

4 A I had a DVT in my leg. I recognized the signs and it was
11:29:40 5 turning purple so I went to my doctor and he sent me to the
6 emergency room, and that's where they diagnosed the PE.

7 Q Now, Lisa, had you had a history of DVT and pulmonary
8 embolism before in the past?

9 A I did. I had a DVT back in late 1989 in my right calf.
11:30:00 10 And then when I had another one in 2009 I recognized what it
11 was and went to my doctor. And that one went to my lungs.
12 That was my first PE.

13 Q So in February of 2011, did you -- I think you told us you
14 knew you had a DVT, a clot.

11:30:18 15 A Yes.

16 Q Did you have any -- were you concerned about a pulmonary
17 embolism at all?

18 A Not at first. Until I got to the hospital.

19 Q But eventually you were diagnosed with that.

11:30:31 20 A Yes.

21 Q And by the way, what hospital were you in?

22 A That would have been Wheaton Franciscan in Franklin,
23 Wisconsin.

24 Q Franklin, Wisconsin?

11:30:41 25 A Yes.

DIRECT EXAMINATION - LISA HYDE

11:30:41 1 Q So did you eventually meet a doctor who told you about IVC
2 filters?

3 A Yes. I met Dr. Henry.

4 Q Do you recall about when -- you were in the hospital a
11:30:53 5 couple days; correct?

6 A I went in the hospital on the 24th and he came in on the
7 25th.

8 Q And from meeting with Dr. Henry, did he discuss with you
9 the filter and the procedure you would need?

11:31:04 10 A He did. He recommended the IVC filter.

11 Q And based upon the discussion with Dr. Henry, what was
12 your understanding about the filter in terms of what it would
13 be for and how long you would have it?

14 A My understanding was it was a temporary filter but he said
11:31:21 15 they were just leaving them in. So it would be a permanent
16 filter for me. And that if for some reason the anticoagulants
17 didn't stop a clot from forming, that this filter would catch
18 anything.

19 Q And how did you feel about that?

11:31:39 20 A I felt like it was extra protection just in case. I
21 wanted to be around for my family, and so I was going to do
22 anything. And it sounded good to me, so --

23 Q And so was the Bard IVC filter implanted on February 25,
24 2011?

11:31:54 25 A Yes.

DIRECT EXAMINATION - LISA HYDE

11:31:56 1 Q And, by the way, we heard from Mark. But at this time had
2 he relocated?

3 A He had relocated the month before to Las Vegas.

4 Q And you remained in Wisconsin why?

11:32:11 5 A I remained in Wisconsin because it was Katelyn's senior
6 year and she wanted to graduate at her high school. We
7 weren't going to move her in the middle of her senior year.

8 Q Was Nate out of the house by then?

9 A Yes. He was in college in Madison.

11:32:26 10 Q What about Grace, how old was she then?

11 A She was -- when the filter was put in she was nine.

12 Q So were you eventually discharged from the hospital after
13 you received your filter?

14 A Yes. I was discharged on the 28th of February.

11:32:42 15 Q By the way, there's been some discussion about protein C
16 deficiency. When did that diagnosis occur?

17 A At the same time. They diagnosed me during my hospital
18 stay.

19 Q And so when you were diagnosed with pulmonary embolism and
11:32:56 20 DVT, did you finally learn what may be the reason you had
21 that?

22 A Yes. They suggested it was a protein C deficiency and I
23 saw a hematologist right after leaving the hospital.

24 Q So as we talk about your timeline and your story, did you
11:33:14 25 eventually take Katelyn and Grace to Las Vegas?

DIRECT EXAMINATION - LISA HYDE

11:33:21 1 A Yes.

2 Q And when did you and the two daughters arrive?

3 A Would have been in August. Right before school started.

4 Q August of 2011?

11:33:33 5 A 2011, yes.

6 Q And how was life going there?

7 A Life was going good.

8 Q And Mark was working with air traffic controller there?

9 A Yes.

11:33:45 10 Q Were you working at that time?

11 A No. When I had Grace, I stayed home. I became a

12 stay-at-home mom.

13 Q And so just to put it all in context, did Katelyn graduate

14 high school by this time?

11:33:57 15 A Yes.

16 Q And where did she go to? Did she move to Las Vegas with

17 you?

18 A She did. She was going to UNLV in Las Vegas.

19 Q And what about Grace, was she in school yet by the time

11:34:09 20 you moved?

21 A Yes, she started 4th grade after we moved.

22 Q All right. So you were in Las Vegas. And did the Bard

23 filter ever become an issue again?

24 A It did.

11:34:23 25 Q When?

DIRECT EXAMINATION - LISA HYDE

11:34:23 1 A May of 2014. I went in for a checkup with my doctor to
2 check my pro time. I was on warfarin at the time.

3 Q There was also a suggestion you may have had back pain at
4 the time?

11:34:35 5 A Yeah, I had back pain. And I also thought there was blood
6 in my urine. I wanted him to check me for a UTI or kidney
7 stone.

8 Q How did that --

9 A It was negative. Urine test was negative. But he -- with
11:34:48 10 pressure there was some pain, so he ordered a CT scan.

11 Q And the CT scan, did you have an idea what part of your
12 anatomy it was going to view?

13 A The abdomen.

14 Q And how long were you with the doctor that day?

11:35:02 15 A How long was I with the doctor?

16 Q Yes. You weren't admitted to a hospital --

17 A No. No. I had the CT scan done a week later or ten days.

18 Q And then you returned home. Did you ever receive any
19 information about that CT scan?

11:35:17 20 A I received a phone call from Dr. Sparks' office and they
21 requested I go have a chest X-ray done because they found
22 something on the CT scan.

23 Q And when you would go to Dr. Sparks' office, is that Dr.
24 Amy Sparks?

11:35:32 25 A Amy Sparks, but I was seeing her physician's assistant.

DIRECT EXAMINATION - LISA HYDE

11:35:37 1 Q What is his name?

2 A Jay Cology.

3 Q Did you have any idea why you needed to go in and get a

4 chest X-ray?

11:35:44 5 A No. They mentioned -- it was a receptionist at the

6 doctor's office, and she mentioned that they thought there was

7 something left behind during a procedure. That's all I knew

8 at that the point.

9 Q Did you even know what procedure --

11:35:58 10 A No.

11 Q -- they were talking about?

12 A No.

13 Q So did you go get the chest X-ray?

14 A Yes.

11:36:05 15 Q And then after you had the X-ray, did you return home?

16 A I did.

17 Q And at any point in time did you learn about the chest

18 X-ray and what it showed?

19 A Jay called me on May 22nd of 2014 and said that the chest

11:36:23 20 X-ray verified my IVC filter had fractured and that a piece of

21 it went to my heart.

22 Q And you were at home then?

23 A Yes. I was just cleaning and he called me.

24 Q Tell us how you felt when you received that phone call.

11:36:35 25 A I felt surprise. I felt terrified. I didn't expect this

DIRECT EXAMINATION - LISA HYDE

11:36:40 1 to happen. I thought it was going to protect me, and now I
2 found out it fractured.

3 Q Did you follow up with Dr. Sparks or Jay Cology?

4 A Yes. I went and saw Jay the next day in the doctor's
11:36:54 5 office.

6 Q Was Jay seeing you for other issues at that time?

7 A He was seeing me to check my pro time and make sure my
8 blood was at the right levels.

9 Q Did he have a discussion at all with you about the -- you
11:37:09 10 understood now that there was a piece of the IVC filter and it
11 was in the right ventricle of your heart?

12 A Yes.

13 Q Did you have any discussion about that?

14 A I did. I asked him what do we do now? And he said we're
11:37:23 15 going to check it again in six to 12 months.

16 Q What did you think about that?

17 A I said that doesn't seem right. So I asked for copies of
18 the CT scan and chest X-ray.

19 Q Why did you ask for copies of your records?

11:37:40 20 A I -- it just didn't seem right to me. I wanted to look
21 them over myself and see what he was talking about.

22 When I looked at them, I had a nodule on my lung that
23 showed up on the chest X-ray.

24 Q Did Mr -- is it Cology?

11:37:55 25 A Cology.

DIRECT EXAMINATION - LISA HYDE

11:37:56 1 Q Cology. Did he indicate to you whether he or Dr. Sparks
2 had any prior experience with fractured IVC filters?

3 A No --

4 MS. HELM: Objection, Your Honor.

11:38:06 5 THE COURT: Excuse, me ma'am.

6 MS. HELM: Hearsay.

7 THE COURT: What's your response on hearsay?

8 MR. O'CONNOR: I'm going through questions and
9 statements for purposes of a medical diagnosis and treatment.

11:38:17 10 THE COURT: Those are patient statements.

11 MR. O'CONNOR: I understand that.

12 BY MR. O'CONNOR:

13 Q What was your impression --

14 Got that. Thanks.

11:38:25 15 A My impression was he was flustered and very confused with
16 the results.

17 Q And so what did you do?

18 A I went home and I started doing some research and I
19 thought, well, if it's in my heart I'll call some
11:38:39 20 cardiologists.

21 Q Did you contact a cardiologist?

22 A I did. I contacted a couple, and the soonest they could
23 see me was June 9th of 2014.

24 Q And so what time period are we talking about when you made
11:38:51 25 the calls?

DIRECT EXAMINATION - LISA HYDE

11:38:52 1 A I made -- well, I had that appointment with Jay on
2 May 23rd. I'm sure I made the calls the next day.

3 Q And was -- when was the first time you could get in to see
4 a cardiologist?

11:39:04 5 A June 9th.

6 Q And who was the cardiologist?

7 A Dr. Shehane.

8 Q And did you do any other research at that time?

9 A I did. While I was researching the filter and what
11:39:20 10 happens if it fractures, I found Dr. Kuo.

11 Q Did you contact Dr. Kuo's office?

12 A I did. I contacted his office.

13 Q And did Dr. Kuo ever contact you, call you?

14 A Yes.

11:39:34 15 Q Now, in relation -- you said your appointment was June
16 when?

17 A June 9th.

18 Q Was that with Doctor Shehane?

19 A That was with Dr. Shehane, yes.

11:39:43 20 Q He a cardiologist in Las Vegas?

21 A Yes.

22 Q In relation to that appointment, when did Dr. Kuo call you
23 back?

24 A Dr. Kuo called me on June 24th of 2014.

11:39:55 25 Q Before you talked to Dr. Kuo, then, you saw Dr. Shehane?

DIRECT EXAMINATION - LISA HYDE

11:39:59 1 A Yes.

2 Q And when you saw Dr. Shehane, did you bring your imaging
3 studies?

4 A I did. He was very surprised that they caught the right
11:40:10 5 ventricle on my CT scan. I feel like it was by the grace of
6 God. I couldn't believe it. They went extra wide and just
7 happened to capture that fracture piece.

8 Q I see. Is that because the CT scan was supposed to cover
9 an area lower?

11:40:24 10 A It was lower right abdomen. He happened to expand the
11 scan for whatever reason.

12 Q So from your discussion with Dr. Shehane, did you
13 understand that finding of that strut was incidental?

14 A Oh, yes. It was amazing.

11:40:38 15 Q And did you tell Dr. Shehane at that time concerns you had
16 about the filter strut in your right ventricle?

17 A I did. And Dr. Shehane didn't -- he wasn't that familiar
18 with the IVC filter either at that time, so he ordered an
19 echocardiogram and he said he'd just do a lot research on it
11:41:04 20 and we'd meet back.

21 Q So did you have a follow up -- when you saw Dr. Shehane
22 June 9, did you have a plan to follow up with him?

23 A Yes. On June 25th.

24 Q And so you returned home. Did you go through the tests
11:41:18 25 that Dr. Shehane had ordered for you?

DIRECT EXAMINATION - LISA HYDE

11:41:21 1 A Yes.

2 Q And the plan was that you were going to go back to him
3 when?

4 A June 25th.

11:41:27 5 Q And in between then you received a call from Dr. Kuo?

6 A Received a call from Dr. Kuo the day before, on the 24th.

7 Q And in that call did you tell Dr. Kuo about what had been
8 found about the strut in your right ventricle?

9 A Yes. At that point he actually had my medical records.

11:41:45 10 So he had the scans.

11 Q And based upon the conversations with Dr. Kuo, what was
12 your understanding as to what he could do for you?

13 A My understanding was it could come -- he could get the
14 filter out and he was going to try to get the piece out of my
11:42:02 15 heart. He wasn't sure, though, if he could do it.

16 Q Was it your understanding that the piece -- he may not be
17 able to remove the piece?

18 A Yes. He said he wouldn't know until he got in there.

19 Q And what did that mean to you if the strut couldn't be
11:42:16 20 removed when you saw Dr. Kuo?

21 A If it couldn't be removed?

22 Q Yes.

23 A It meant to me I would have to have open-heart surgery.

24 Q All right. Now, you understood that Dr. Kuo was in
11:42:29 25 Stanford near Palo Alto, California.

DIRECT EXAMINATION - LISA HYDE

11:42:31 1 A Yes.

2 Q But you decided that you would follow up and see him at
3 some point in time?

4 A The research I had done, Dr. Kuo was the best, the best in
11:42:43 5 the world, so I didn't think it was that far to go, actually.

6 Q Did you set a time -- did you have a date set when you
7 would go in to see Dr. Kuo for the procedure?

8 A Yes. The soonest he could do the procedure was
9 August 26th.

11:42:58 10 Q How did you feel about that?

11 A I felt a little scared. I had been waiting and kind of
12 wanting to get it done.

13 Q Did you return to Dr. Shehane in the meantime?

14 A I did. I saw Dr. Shehane the next day.

11:43:11 15 Q Did you tell Dr. Shehane you had the conversation with
16 Dr. Kuo?

17 A Yes.

18 Q Did Dr. Shehane examine you that day and did he consult
19 with you about the strut in your heart?

11:43:25 20 A Yes. What he said was that we really don't know --

21 MS. HELM: Excuse me. I'm sorry to interrupt --

22 BY MR. O'CONNOR:

23 Q Just follow me on that because I don't want you to talk
24 about what he told you, but what I would like you to tell us
11:43:36 25 is based upon your meeting with Dr. Shehane, number one, I

DIRECT EXAMINATION - LISA HYDE

1 think you told us you advised him you had seen Dr. Kuo -- or
2 talked to Dr. Kuo.

3 A Yes.

4 Q And did you also have any plans with Mark to travel during
5 this time?

6 A Yes. We had a trip to Wisconsin planned.

7 Q And how did you feel about that trip to Wisconsin with all
8 you had just learned about the strut in your right ventricle,
9 you were going to have a procedure with Dr. Kuo, and here you
10 were in a cardiologist's office?

11 A We asked if it was okay if we still made the trip. I was
12 apprehensive about it. But I thought if this is going to cut
13 through, I want to see my family, I want to see my friends, I
14 want to say goodbye. I'm sorry.

15 It was important to me to take the trip.

16 If Dr. Shehane had said don't take the trip, we would
17 have canceled it.

18 Q So you did talk to Dr. Shehane about the trip; is that
19 right?

20 A Yes.

21 Q And the trip sounds like it became even -- took on a whole
22 different importance to you.

23 A It did.

24 Q So in your meeting, did you -- and your consult with
25 Dr. Shehane, did you decide or make any decisions as to what

DIRECT EXAMINATION - LISA HYDE

11:45:09 1 you needed to do or look out for as you made this trip to
2 Wisconsin?

3 A Yes. He said if the --

4 MS. HELM: I'm sorry --

11:45:20 5 BY MR. O'CONNOR:

6 Q Hang on. I just want to know what your understanding was
7 from that consult.

8 A My understand was if it would cut through the wall of my
9 heart I would know it and I needed to get to a hospital right
11:45:30 10 away, especially since I was on a blood thinner.

11 Q Was Mark, your husband, with you?

12 A Yes.

13 Q He was there when Dr. Shehane talked to you?

14 A Yes, he was.

11:45:39 15 Q Did Dr. Shehane -- were you advised that you could contact
16 Dr. Shehane if necessary?

17 A Yes. He handed us his business card and advised that we
18 give it to -- if we end up at a hospital, we give that to them
19 and they can call him and he will explain the situation.

11:45:59 20 Q So you went on the trip to Wisconsin to see family.

21 A Yes.

22 Q Who was there?

23 A My sister, her husband, her children, Mark's brother, his
24 wife, their children. Mark's Aunt Betty. Our daughter
11:46:12 25 Katelyn of course. And I -- I actually saw a lot of my

DIRECT EXAMINATION - LISA HYDE

11:46:18 1 cousins and my last remaining aunt.

2 Q And is this trip something that you would do every year?

3 A We would try to make a trip once a year, yes.

4 Q So based upon your conversations with Dr. Kuo and your
11:46:38 5 conversation with Dr. Shehane, did that change how you would
6 proceed on this trip?

7 A Yes. It wasn't as happy as past trips. Because, like I
8 said, I thought this was it. It was my final goodbye to
9 everyone. I didn't tell them that.

11:46:54 10 Q You were concerned?

11 A I was very concerned.

12 Q Eventually you got through the trip and saw the family and
13 then you returned to Las Vegas.

14 A Yes.

11:47:08 15 Q And it sounds like the next thing you and Mark had to do
16 was plan another trip.

17 A Right.

18 Q And that was to go to Stanford.

19 A Yes.

11:47:17 20 Q How were you feeling about making that trip to see
21 Dr. Kuo?

22 A I was feeling incredibly scared.

23 Q Your daughter Grace was still home?

24 A She was. She was 12.

11:47:31 25 Q Were you in regular contact with the other two children,

DIRECT EXAMINATION - LISA HYDE

11:47:33 1 Nate and Katelyn?

2 A Yes.

3 Q And you were scared. Did you have any thoughts about your

4 children during this time?

11:47:42 5 A Yes. I wrote letters to each one, I wrote a letter to

6 Mark, just in case. It was kind of my goodbye to them.

7 Q Now, we heard from Mark, an air-traffic controller who

8 insisted on driving, that you drove to Stanford.

9 A Yeah.

11:48:02 10 Q And you arrived to Stanford. And do you remember when you

11 met Dr. Kuo?

12 A I met Dr. Kuo on the 25th of August.

13 Q And did you also meet his assistant?

14 A Yes.

11:48:13 15 Q During that time, did you provide the assistant and

16 Dr. Kuo with a history?

17 A Yes, I did.

18 Q And tell us what that history included.

19 A It included -- I had been feeling dizzy. I had been

11:48:28 20 feeling weak, fatigued. I developed back pain. Eventually

21 some chest discomfort, kind of fluttering. I mentioned all

22 this during the exam.

23 Q And these are issues that you had been experiencing in the

24 past?

11:48:48 25 A I'd been experiencing them for about a year and a half.

DIRECT EXAMINATION - LISA HYDE

11:48:51 1 Q Had you seen any doctors for these conditions? I think
2 you said -- what did you say? Dizziness. Did you say
3 fluttering?

4 A Yes. That came later but --

11:49:01 5 Q Back pain.

6 A Initially dizziness, fatigue. My whole body was fatigued.

7 Q Did you have back pain?

8 A I had back pain.

9 Q When you had saw other doctors for these, did you get any
11:49:11 10 answers, any diagnoses as to what was causing these?

11 A They sent me through physical therapy for the dizziness.
12 Then another physical therapist for the back pain. I was sent
13 to a rheumatologist because my primary doctor thought I had
14 fibromyalgia.

11:49:31 15 Q Did you?

16 A No. The rheumatologist didn't think it was fibromyalgia.
17 I was sent to pain management. He couldn't figure out what
18 was going on.

19 Q Did you feel that in talking with Dr. Kuo's assistant and
11:49:45 20 Dr. Kuo himself that you received some answer to questions as
21 to why you had those problems for that time?

22 A I felt validated, yes. Absolutely.

23 Q And what was your understanding as to what may have been
24 causing those symptoms after your first meeting with Dr. Kuo
11:50:07 25 in person?

DIRECT EXAMINATION - LISA HYDE

11:50:08 1 A With Dr. Kuo? That's when I found out the filter was
2 actually perforating the vein and it was touching my aorta and
3 it was also interfering with my spine.

4 Q Did you learn that the filter was perforating through to
11:50:20 5 both the aorta and a lumbar vertebrae, I think we heard it was
6 L3?

7 A Yes.

8 Q And then in addition, you had a piece that was in the
9 right ventricle of your heart?

11:50:30 10 A Right. I also had leg pain. I forgot to mention that.
11 That was pretty intense.

12 Q Now, how was that night before surgery?

13 A It was scary. It was scary. Dr. Kuo had mentioned that
14 the filter was probably going to fracture as he pulled it out,
11:50:54 15 that he would chase down the pieces wherever they went. It
16 kind of frightened me.

17 Q How did you go -- you went into the surgery?

18 A Yes.

19 Q And the surgery was completed.

11:51:09 20 A Yes.

21 Q Now, Lisa, I just want to take you back to February 24,
22 25, of 2011 when you met Dr. Henry and you decided to have the
23 filter that you thought was going to provide benefit to you.
24 Do you recall that testimony?

11:51:30 25 A Yes.

DIRECT EXAMINATION - LISA HYDE

11:51:31 1 Q Did you ever have any reason to believe or expect that the
2 Bard filter inside of you would penetrate through the walls of
3 your vena cava?

4 A No.

11:51:40 5 Q Did you have any reason to ever think that the legs of the
6 filter would perforate through and penetrate your aorta?

7 A No.

8 Q Did you ever think or become concerned that that filter
9 could go through and actually penetrate to your vertebrae in
11:51:58 10 your back?

11 A Not at all.

12 Q Did you ever expect or have any reason to expect that the
13 filter that you thought was going to help you would break and
14 land a piece in the right ventricle of your heart?

11:52:18 15 A No.

16 Q You made it through your surgery. You heard from Dr. Kuo.
17 Did you get back home?

18 A Yes.

19 Q And how were things when you got back home?

11:52:35 20 A I was real relieved it was out, but I -- I still have
21 panic at night after I go to sleep. Sometimes I wake -- most
22 nights, actually, I wake up just in a panic thinking that I'm
23 dead or I'm dying and I need to ground myself. I need to jump
24 out of bed, I need to touch something. Sometimes,
11:53:02 25 unfortunately, it's my poor husband. But, yeah, it's just

CROSS-EXAMINATION - LISA HYDE

11:53:09 1 kind of a residual effect.

2 Q How often?

3 A Basically every night. Sometimes multiple times a night.

4 Q Now, can you tell the members of the jury after all you've
11:53:26 5 been through with the Bard filter and the procedures you went
6 through and the things that had to cross your mind, what type
7 of impact has that had on you?

8 A It's made me realize you can't take life for granted. You
9 have to just be with your loved ones and spend as much time
11:53:53 10 with them and never take anything for granted because you
11 never know what can happen.

12 Q And, again, did you ever have any reason to think that
13 this device that was supposed to protect you would land you in
14 a hospital to have the surgery that you did?

11:54:08 15 A No. That was supposed to be my backup.

16 MR. O'CONNOR: I think that's all I have. Thank you.

17 THE COURT: All right. Cross-examination.

C R O S S - E X A M I N A T I O N

18
19 BY MS. HELM:

11:54:39 20 Q Good morning, Ms. Hyde.

21 A Good morning.

22 Q I had to check the clock to make sure.

23 Are you okay to proceed?

24 A Yes.

11:54:46 25 Q Okay. I want to follow up just a little bit about some of

CROSS-EXAMINATION - LISA HYDE

11:54:49 1 your medical history and medical treatment that has occurred
2 from 2 -- I'm going to start early '90s and talk about some of
3 your medical treatment.

4 A Okay.

11:55:02 5 Q You were first diagnosed with a DVT in approximately 1989
6 or 1990; right?

7 A Correct.

8 Q And at that time I believe it was your testimony that they
9 attributed it maybe to birth control pills?

11:55:16 10 A At that time, yes.

11 Q Yes. And you received some temporary treatment of
12 anticoagulants; is that right?

13 A Correct.

14 Q And then the next time you were diagnosed with a DVT was
11:55:30 15 2009; is that right?

16 A Yes.

17 Q That was actually both a DVT and a pulmonary embolism; is
18 that right?

19 A Yes.

11:55:37 20 Q And, again, you were treated with anticoagulants
21 medication; is that right?

22 A That's right.

23 Q Was it Coumadin at that time?

24 A It was.

11:55:46 25 Q And were you still on Coumadin in February of 2011 or had

CROSS-EXAMINATION - LISA HYDE

11:55:50 1 you stopped taking it?

2 A I had stopped taking it. It was just for six months after
3 the 2009 clot.

4 Q But again in 2011 you experienced both a DVT and pulmonary
11:56:03 5 embolism; is that right?

6 A Yes.

7 Q And do you recall describing the pulmonary embolism you
8 had as massive clots?

9 A It was massive. Yes.

11:56:13 10 Q You were hospitalized, in fact, because of those clots;
11 correct?

12 A Yes.

13 Q And it was during that hospitalization in 2011 that you
14 were put back on anticoagulants; is that right?

11:56:27 15 A Yes.

16 Q And you received the IVC filter.

17 A Correct.

18 Q And you were diagnosed with protein C deficiency.

19 A Yes. Um-hmm.

11:56:38 20 Q So you understood in 2011 -- well, you found a source for
21 your blood clotting; correct?

22 A Correct.

23 Q Okay. And since then, have you been consistently on
24 anticoagulants?

11:56:50 25 A I have.

CROSS-EXAMINATION - LISA HYDE

11:56:51 1 Q And you know what anticoagulants are because you take
2 them, but for the jury, those are commonly called blood
3 thinners; is that right?

4 A That's right.

11:57:00 5 Q And you've taken Coumadin; is that right?

6 A I was on warfarin until May of 2014.

7 Q And in May of 2014 you changed to Xarelto; correct?

8 A Yes.

9 Q You're still taking Xarelto today; is that right?

11:57:13 10 A Yes.

11 Q Between February of 2011 and May of 2014, you had medical
12 treatment, didn't you?

13 A Yes.

14 Q You moved to Las Vegas and originally had Dr. Sparks and
11:57:37 15 her office as your primary care provider; correct?

16 A Correct.

17 Q You also had other medical treatment during that time;
18 correct?

19 A Correct.

11:57:43 20 Q And in that time period, from February of 2011 to May of
21 2014, none of those treating physicians ever mentioned your
22 filter to you; correct?

23 A Correct.

24 Q And you never mentioned it to them; correct?

11:57:57 25 A Well, they knew I had a filter.

CROSS-EXAMINATION - LISA HYDE

11:57:59 1 Q They knew you had a filter.

2 A Every doctor I've ever seen, that's probably the first
3 thing out of my mouth.

4 Q You mentioned that you have some trouble sleeping and you
11:58:08 5 wake up with -- you wake up in the middle of the night.

6 A Yes.

7 Q You were actually diagnosed with sleep apnea and waking
8 up, and the shaking and waking up, as early as the 2000s;
9 right?

11:58:21 10 A I was waking up -- it was different. I was waking up
11 because I would stop breathing. But I think it was more
12 mid-2000s. But I am on a CPAP.

13 Q And that CPAP was actually diagnosed or recommended for
14 you back in the early 2000s when you were first diag --

11:58:39 15 A Mid 2000s.

16 Q I'm sorry, mid 2000s. Okay.

17 And have you been consistently on the CPAP since then
18 or did you stop using it and start?

19 A I use the CPAP every night.

11:58:53 20 Q You also have asthma, don't you?

21 A Yes.

22 Q And you were diagnosed with asthma back again in the early
23 2000s?

24 A It was around the same time.

11:59:03 25 Q And the asthma causes coughing, wheezing, trouble

breathing, shortness of breath?

A I have coughing. I've never really had the wheezing. It's mild persistent asthma and it's controlled with my inhaler.

Q But it's gotten somewhat worse with age, hasn't it?

A It got worse with age, but once I started on the inhaler, it is controlled.

THE COURT: Ms. Helm, we're going to break at this point.

Members of the jury, we'll resume at 1 o'clock.

We'll excuse you at this time.

(The jury exited the courtroom at 12:00.)

THE COURT: All right. Will we see you at 1 o'clock.

MR. ROGERS: Thank you, Your Honor.

(Recess taken at 12:00.)

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 28th day of September, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter